Neuropsych II Annotated CRF

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Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Demographics

Pilot Transfusion Trial

{visit.label}

Subject ID:

Site:

Completion Date: DE	EMO:TODAYDA / DEMO:TODAYYR		
	DD MMM YYYY		
Date of birth: DEMO:	DOBDA / DEMO:DOBMO / DEMO:DOBYR		
1	MMM YYYY		
Age:	☐ (DEMO:AGE) 21-29 ☐ (DEMO:AGE) 30-39 ☐ (DEMO:AGE) 40-49	(DEMO:AGE) 50-55	
Gender:	(DEMO:GENDER) Male (DEMO:GENDER) Female		
Race:	(DEMO:AMERIND) American Indian/Alaska Native (DEMO:ASIAN) Asian (DEMO:AFRAMER) Black or African-American (DEMO:HAWAII) Native Hawaiian or other Pacific Islander (DEMO:WHITE) White		
Ethnicity:	(DEMO:RACEOT) Other, specify: DEMO:RACEOTS (DEMO:ETHNIC) Hispanic or Latino (DEMO:ETHNIC) Not Hispanic or Latino		
Select highest grade		grade ▼	
Hemoglobin Elect	trophoresis:		
Date:	DEMO: ELECDA / DEMO: ELECMO / DEMO: ELECYR DD MMM YYYY	Diagnosis:	☐ (DEMO:DIAGNOS) SS ☐ (DEMO:DIAGNOS) SB 0 ☐ (DEMO:DIAGNOS) AA (control group)
A (%)	DEMO: HGBA		
S (%)	DEMO: HGBS		
F (%)	DEMO: HGBF		
A2 (%)	DEMO: HGBA2		
Other (%)	DEMO: HGBOTH Specify: DEMO: HGBOTHS		
Pregnancy Test			
(DEMO:PREGND)	Not done, subject male	Date of Collection:	/ DEMO: COLLMO / DEMO: COLLYR
(DEMO:PREGND)	Not done, female subject not of child-bearing potential (check only one reason below)	DD	MMM YYYY
	(DEMO:REASND) Postmenopausal	Type: (DEMO:TYPE)	
	(DEMO:REASND) Hysterectomy	Result: DEMO:RESUL	T) Positive (DEMO:RESULT) Negative
	(DEMO:REASND) Tubal ligation		
	(DEMO:REASND) Other, specify:		
	DEMO:REASNDS		

Comments for page: DEMO: COMMENT

Submit Query Cancel Form Completion Help Print Rho

Neuropsychological
Dysfunction and
Neuroimaging
Abnormalities in
Neurologically Intact
Adult Patients With
Sickle Cell Disease

Mini-Mental Status Examination

Pilot Transfusion Trial

{visit.label}

Subject ID:

Score

Site:

Date of Assessment: MMSE:TODAYDA / MMSE:TODAYMO / MMSE:TODAYYR

DD MMM YYYY

Orientation (1 pt. each)

Ask the patient: "What is the year, season, date, day, month?"

MMSE:MMSE1 /5

2. Ask: "Where are you?" — State, country, town, place, floor (or ward)

MMSE:MMSE2 /5

Memory registration(3 pts. if correct first time, 2 if correct second time, 1 if correct third time)

3. Tell the patient that you want him/her to remember something for you, then name three unrelated objects (speak clearly and slowly). Ask the patient to repeat the three objects. Ask the patient to keep the three things in mind.

MMSE:MMSE3 /3

Attention and concentration (1 pt. for each correct answer OR 1 pt. for each correct letter)

4. Ask the patient to take seven from 100, then seven from the result, and so on for five subtractions.

OR

MMSE:MMSE4 /5

Ask the patient to spell "world" backwards.

Memory recall (1 pt. each)

5. Ask the patient to recall the three objects from test 3.

MMSE:MMSE5 /3

Language (1 pt. for each or 1 pt. for each part of each question)

6. Show the patient two familiar objects and ask him/her to name them.

MMSE:MMSE6 /2

7. Ask the patient to repeat a sentence after you: "No ifs, ands or buts."

MMSE:MMSE7 /1

8. Ask the patient to follow a three-stage command: "Please take this paper in your left hand, fold it in half and put the paper on the floor."

MMSE:MMSE8 /3

9. Ask the patient to read and follow a written instruction, e.g., "Close your eyes."

MMSE:MMSE9 /1

Ask the patient to write a simple sentence. The sentence should contain a subject and a verb and should make sense.

MMSE:MMSE10

11. Ask the patient to copy a picture of intersecting pentagons.

MMSE:MMSE11

/1

MMSE:MMSETOT

/30

A score below 24 indicates probable cognitive impairment. A score below 17 indicates definite cognitive impairment. For subjects who are not literate, parameters 4, 9 and 10 may not be assessable and the total score may be less than 30.

Comments for page: MMSE: COMMENT

Total score

Submit Query

Cancel

Form Completion Help

Print

x Rho

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Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

18.

19.

Blue

Energetic

Profile of Mood States Pilot Transfusion Trial Subject ID:

					Site:	
Date of as	ssessment: POMS: AS	SSDA / POMS:ASSMO /	POMS:ASSYR			
	DD	MMM	YYYY			
Then fill in O	et of words that describe for NE circle under the answe	eelings people have. Please er to the right which best des URING THE PAST WEEK IN	scribes			
		Not at all	A little	Moderately	Quite a bit	Extremely
1.	Friendly	□ (POMS:POMS1) 0	□ (POMS:POMS1) 1	□ (POMS:POMS1) 2	□ (POMS:POMS1) 3	□ (POMS:POMS1) 4
2.	Tense	□ (POMS:POMS2) 0	□ (POMS:POMS2) 1	□ (POMS:POMS2) 2	□ (POMS:POMS2) 3	□ (POMS:POMS2) 4
3.	Angry	□ (POMS:POMS3) 0	□ (POMS:POMS3) 1	□ (POMS:POMS3) 2	□ (POMS:POMS3) 3	□ (POMS:POMS3) 4
4.	Worn out	□ (POMS:POMS4) 0	□ (POMS:POMS4) 1	□ (POMS:POMS4) 2	□ (POMS:POMS4) 3	□ (POMS:POMS4) 4
5.	Unhappy	□ (POMS:POMS5) 0	□ (POMS:POMS5) 1	□ (POMS:POMS5) 2	□ (POMS:POMS5) 3	□ (POMS:POMS5) 4
6.	Clear-headed	□ (POMS:POMS6) 0	□ (POMS:POMS6) 1	□ (POMS:POMS6) 2	□ (POMS:POMS6) 3	□ (POMS:POMS6) 4
7.	Lively	□ (POMS:POMS7) 0	□ (POMS:POMS7) 1	□ (POMS:POMS7) 2	□ (POMS:POMS7) 3	□ (POMS:POMS7) 4
8.	Confused	□ (POMS:POMS8) 0	□ (POMS:POMS8) 1	□ (POMS:POMS8) 2	□ (POMS:POMS8) 3	□ (POMS:POMS8) 4
9.	Sorry for things done	□ (POMS:POMS9) 0	□ (POMS:POMS9) 1	□ (POMS:POMS9) 2	□ (POMS:POMS9) 3	□ (POMS:POMS9) 4
10.	Shaky	□ (POMS:POMS10) 0	□ (POMS:POMS10) 1	□ (POMS:POMS10) 2	\Box (POMS:POMS10)	□ (POMS:POMS10) 4
11.	Listless	□ (POMS:POMS11) 0	□ (POMS:POMS11) 1	□ (POMS:POMS11) 2	□ (POMS:POMS11) 3	□ (POMS:POMS11) 4
12.	Peeved	□ (POMS:POMS12) 0	□ (POMS:POMS12) 1	□ (POMS:POMS12) 2	□ (POMS:POMS12)	□ (POMS:POMS12) 4
13.	Considerate	□ (POMS:POMS13) 0	□ (POMS:POMS13) 1	□ (POMS:POMS13) 2	□ (POMS:POMS13) 3	□ (POMS:POMS13) 4
14.	Sad	□ (POMS:POMS14) 0	□ (POMS:POMS14) 1	□ (POMS:POMS14) 2	□ (POMS:POMS14)	□ (POMS:POMS14) 4
15.	Active	□ (POMS:POMS15) 0	□ (POMS:POMS15) 1	□ (POMS:POMS15) 2	□ (POMS:POMS15)	□ (POMS:POMS15) 4
16.	On edge	□ (POMS:POMS16) 0	□ (POMS:POMS16) 1	□ (POMS:POMS16) 2	□ (POMS:POMS16)	□ (POMS:POMS16) 4
17.	Grouchy	□ (POMS:POMS17)	□ (POMS:POMS17)	□ (POMS:POMS17)	□ (POMS:POMS17)	□ (POMS:POMS17)

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 $\ \, \Box \text{(POMS:POMS18)} \ \, \Box \text{(POMS:POMS18)} \ \, \Box \text{(POMS:POMS18)} \ \, \Box \text{(POMS:POMS18)} \ \, \Box \text{(POMS:POMS18)}$

 $\ \, \Box \, (\text{POMS:POMS19}) \ \, \Box \, (\text{POM$

20.	Panicky	□ (POMS:POMS20) 0	□ (POMS:POMS20)	□ (POMS:POMS20)	□ (POMS:POMS20)	□ (POMS:POMS20)
21.	Hopeless	□ (POMS:POMS21) 0	□ (POMS:POMS21)	□ (POMS:POMS21)	□ (POMS:POMS21)	□ (POMS:POMS21)
22.	Relaxed	□ (POMS:POMS22) 0	□ (POMS:POMS22)	□ (POMS:POMS22) 2	□ (POMS:POMS22)	□ (POMS:POMS22) 4
23.	Unworthy	□ (POMS:POMS23) 0	□ (POMS:POMS23) 1	□ (POMS:POMS23) 2	□ (POMS:POMS23) 3	□ (POMS:POMS23) 4
24.	Spiteful	□ (POMS:POMS24) 0	□ (POMS:POMS24) 1	□ (POMS:POMS24) 2	□ (POMS:POMS24) 3	□ (POMS:POMS24) 4
25.	Sympathetic	□ (POMS:POMS25) 0	□ (POMS:POMS25) 1	□ (POMS:POMS25) 2	□ (POMS:POMS25) 3	□ (POMS:POMS25) 4
26.	Uneasy	□ (POMS:POMS26) 0	□ (POMS:POMS26) 1	□ (POMS:POMS26) 2	□ (POMS:POMS26) 3	□ (POMS:POMS26) 4
27.	Restless	□ (POMS:POMS27) 0	□ (POMS:POMS27) 1	□ (POMS:POMS27) 2	□ (POMS:POMS27) 3	□ (POMS:POMS27) 4
28.	Unable to concentrate	□ (POMS:POMS28) 0	□ (POMS:POMS28) 1	□ (POMS:POMS28) 2	□ (POMS:POMS28)	□ (POMS:POMS28) 4
29.	Fatigued	□ (POMS:POMS29) 0	□ (POMS:POMS29) 1	□ (POMS:POMS29) 2	□ (POMS:POMS29)	□ (POMS:POMS29) 4
30.	Helpful	□ (POMS:POMS30) 0	□ (POMS:POMS30) 1	□ (POMS:POMS30) 2	□ (POMS:POMS30) 3	□ (POMS:POMS30) 4
31.	Annoyed	□ (POMS:POMS31) 0	□ (POMS:POMS31) 1	□ (POMS:POMS31) 2	□ (POMS:POMS31)	□ (POMS:POMS31) 4
32.	Discouraged	□ (POMS:POMS32) 0	□ (POMS:POMS32) 1	□ (POMS:POMS32) 2	□ (POMS:POMS32)	□ (POMS:POMS32) 4
33.	Resentful	□ (POMS:POMS33) 0	□ (POMS:POMS33) 1	□ (POMS:POMS33) 2	□ (POMS:POMS33)	□ (POMS:POMS33) 4
34.	Nervous	□ (POMS:POMS34) 0	□ (POMS:POMS34) 1	□ (POMS:POMS34) 2	□ (POMS:POMS34)	□ (POMS:POMS34) 4
35.	Lonely	□ (POMS:POMS35) 0	□ (POMS:POMS35) 1	□ (POMS:POMS35) 2	□ (POMS:POMS35)	□ (POMS:POMS35) 4
36.	Miserable	□ (POMS:POMS36) 0	□ (POMS:POMS36) 1	□ (POMS:POMS36) 2	□ (POMS:POMS36) 3	□ (POMS:POMS36) 4
37.	Muddled	□ (POMS:POMS37) 0	□ (POMS:POMS37) 1	□ (POMS:POMS37) 2	□ (POMS:POMS37)	□ (POMS:POMS37) 4
38.	Cheerful	□ (POMS:POMS38) 0	□ (POMS:POMS38) 1	□ (POMS:POMS38) 2	□ (POMS:POMS38)	□ (POMS:POMS38) 4
39.	Bitter	□ (POMS:POMS39) 0	□ (POMS:POMS39) 1	□ (POMS:POMS39) 2	□ (POMS:POMS39)	□ (POMS:POMS39) 4
40.	Exhausted	□ (POMS:POMS40) 0	□ (POMS:POMS40) 1	□ (POMS:POMS40) 2	□ (POMS:POMS40)	□ (POMS:POMS40) 4
41.	Anxious	□ (POMS:POMS41) 0	□ (POMS:POMS41) 1	□ (POMS:POMS41) 2	□ (POMS:POMS41)	□ (POMS:POMS41) 4
42.	Ready to fight	□ (POMS:POMS42) 0	□ (POMS:POMS42) 1	□ (POMS:POMS42) 2	□ (POMS:POMS42)	□ (POMS:POMS42) 4
43.	Good natured	□ (POMS:POMS43) 0	□ (POMS:POMS43) 1	□ (POMS:POMS43) 2	□ (POMS:POMS43)	□ (POMS:POMS43) 4
44.	Gloomy	□ (POMS:POMS44) 0	□ (POMS:POMS44) 1	□ (POMS:POMS44) 2	□ (POMS:POMS44)	□ (POMS:POMS44) 4
45.	Desperate	□ (POMS:POMS45) 0	□ (POMS:POMS45)	□ (POMS:POMS45)	□ (POMS:POMS45)	□ (POMS:POMS45) 4
46.	Sluggish	□ (POMS:POMS46)				

		0	1	2	3	4
47.	Rebellious	□ (POMS:POMS47) 0	□ (POMS:POMS47) 1	□ (POMS:POMS47) 2	□ (POMS:POMS47) 3	□ (POMS:POMS47) 4
48.	Helpless	□ (POMS:POMS48) 0	□ (POMS:POMS48) 1	□ (POMS:POMS48) 2	□ (POMS:POMS48) 3	□ (POMS:POMS48) 4
49.	Weary	□ (POMS:POMS49) 0	□ (POMS:POMS49) 1	□ (POMS:POMS49) 2	□ (POMS:POMS49) 3	□ (POMS:POMS49) 4
50.	Bewildered	□ (POMS:POMS50) 0	□ (POMS:POMS50) 1	□ (POMS:POMS50) 2	□ (POMS:POMS50) 3	□ (POMS:POMS50) 4
51.	Alert	□ (POMS:POMS51) 0	□ (POMS:POMS51) 1	□ (POMS:POMS51) 2	□ (POMS:POMS51) 3	□ (POMS:POMS51) 4
52.	Deceived	□ (POMS:POMS52) 0	□ (POMS:POMS52) 1	□ (POMS:POMS52) 2	□ (POMS:POMS52) 3	□ (POMS:POMS52) 4
53.	Furious	□ (POMS:POMS53) 0	□ (POMS:POMS53) 1	□ (POMS:POMS53) 2	□ (POMS:POMS53) 3	□ (POMS:POMS53) 4
54.	Efficient	□ (POMS:POMS54) 0	□ (POMS:POMS54) 1	□ (POMS:POMS54) 2	□ (POMS:POMS54) 3	□ (POMS:POMS54) 4
55.	Trusting	□ (POMS:POMS55) 0	□ (POMS:POMS55) 1	□ (POMS:POMS55) 2	□ (POMS:POMS55) 3	□ (POMS:POMS55) 4
56.	Full of pep	□ (POMS:POMS56) 0	□ (POMS:POMS56) 1	□ (POMS:POMS56) 2	□ (POMS:POMS56) 3	□ (POMS:POMS56) 4
57.	Bad-tempered	□ (POMS:POMS57) 0	□ (POMS:POMS57) 1	□ (POMS:POMS57) 2	□ (POMS:POMS57) 3	□ (POMS:POMS57) 4
58.	Worthless	□ (POMS:POMS58) 0	□ (POMS:POMS58) 1	□ (POMS:POMS58) 2	□ (POMS:POMS58) 3	□ (POMS:POMS58) 4
59.	Forgetful	□ (POMS:POMS59) 0	□ (POMS:POMS59) 1	□ (POMS:POMS59) 2	□ (POMS:POMS59) 3	□ (POMS:POMS59) 4
60.	Carefree	□ (POMS:POMS60) 0	□ (POMS:POMS60) 1	□ (POMS:POMS60) 2	□ (POMS:POMS60)	□ (POMS:POMS60) 4
61.	Terrified	□ (POMS:POMS61) 0	□ (POMS:POMS61) 1	□ (POMS:POMS61) 2	□ (POMS:POMS61)	□ (POMS:POMS61) 4
62.	Guilty	□ (POMS:POMS62) 0	□ (POMS:POMS62) 1	□ (POMS:POMS62) 2	□ (POMS:POMS62) 3	□ (POMS:POMS62) 4
63.	Vigorous	□ (POMS:POMS63) 0	□ (POMS:POMS63) 1	□ (POMS:POMS63) 2	□ (POMS:POMS63) 3	□ (POMS:POMS63) 4
64.	Uncertain about things	□ (POMS:POMS64) 0	□ (POMS:POMS64) 1	□ (POMS:POMS64) 2	□ (POMS:POMS64)	□ (POMS:POMS64) 4
65.	Bushed	□ (POMS:POMS65) 0	□ (POMS:POMS65)	□ (POMS:POMS65) 2	□ (POMS:POMS65)	□ (POMS:POMS65) 4
		Mak	e Sure You Have Ans	wered Every Item!		
			From McNair et. al,	1971, 2003.		
Depression:						
Comments for	r page: POMS:COMMENT					
Submit	Query Can	cel	Form Completion	on Help	Print	x Rho

Neuropsychological
Dysfunction and
Neuroimaging
Abnormalities in
Neurologically Intact
Adult Patients With
Sickle Cell Disease

Hematology and Chemistry

Pilot Transfusion Trial

{visit.label}

Subject ID:

Site:

For all subjects in the Pilot Transfusion Phase, labs must be repeated at phase entry, at the 3-month mark, and at the end of the phase. For subjects in the transfusion arm, these labs are also repeated at each pretransfusion visit.

Hematology Collection date:			HEMATOLOG TESTS	Y VALUE
LAB2:HEMADA /	LAB2:HEMAMO /	LAB2:HEMAYR	Hemoglobin (g/dL)	LAB2:HGB
DD	MMM	YYYY	Hemoglobin S (%)	LAB2:HGBS
			Hematocrit (%)	LAB2:HCT
			WBC (x10 ³ / mm ³)	LAB2:WBC
			Neutrophils (%)	LAB2:NEUT
			Platelet count (x10 ³ / ı	mm ³) LAB2:PLATE
Serum Ch	emistry Collect	ion date:	SERUM CHEMIS TESTS	TRY VALUE
LAB2:CHEMDA /	LAB2:CHEMMO /	LAB2:CHEMYR	Creatinine (mg/dL)	LAB2:CREAT
DD	MMM	YYYY	BUN (mg/dL)	LAB2:BUN
	Glucos	se (mg/dL)	☐ (LAB2:GLUCFAS) fasting ☐ (LAB2:GLUCFAS) non-fasting (fasting preferable)	LAB2:GLUC
	AST	· (IU/L)		LAB2:AST
	ALT	(IU/L)		LAB2:ALT
	Tota	al bilirubin (mg/	dL)	LAB2:TOTBILI
	LDH	I (U/L)		LAB2:LDH
	Ferr			

(At entry, ferritin must be < 1,500 ng/mL.)

LAB2:FERRITN

Comments for page: LAB2:COMMENT

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Version: 18 Feb 2009 11

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Intake and Chart Review Pilot Transfusion Trial Subject ID: Site:

Completion Date:	MEDH: TODAYDA	/	MEDH: TODAYMO	/	MEDH: TODAYYR
	DD		MMM		YYYY

Please indicate whether or not there is a past history of the following events and symptoms. For any events marked "Yes", record the onset date of the most recent event in dd/mmm/yy format and answer any specific questions in the comments column. Review the exclusion criteria for any events marked "Yes". Indicate if the condition is ongoing by checking the last column.

	Past History		If II and II are a large to the second secon	Okas I W
Symptom/Event	Yes	No	If "yes", record pertinent comments. Record all date(s) known in the dd/mmm/yy format.	Check if ongoing
Chronic illness (not SCD related) that may affect neurocognitive functioning (exclude if "yes")	□ (MEDH:ILLNES)	□ (MEDH:ILLNES)	Specify Illness(es): MEDH:ILLNESS	□ (MEDH:ILLNESO)
Cancer requiring chemotherapy and/or radiation (exclude if "yes")	□ (MEDH:CANCER)	☐ (MEDH:CANCER)	MEDH: CANCERS	□ (MEDH:CANCERC
History of chronic transfusion (exclude if <u>currently</u> on chronic transfusion)	□ (MEDH:CTRANS)	(MEDH:CTRANS)	MEDH:CTRANSS	□ (MEDH:CTRANSO
Ongoing active infection (such as HIV, tuberculosis, sarcoidosis) (exclude if "yes")	☐ (MEDH:INFECT)	☐ (MEDH:INFECT)	Specify infection: MEDH: INFECTS	□ (MEDH:INFECTO)
Acquired or congenital immune deficiency or disorder (exclude if "yes")	□ (MEDH:IMMUNE)	□ (MEDH:IMMUNE)	Specify disorder: MEDH:IMMUNES	□ (MEDH:IMMUNEO
Active hepatitis (exclude if "yes")	□ (MEDH:HEPAT)	□ (MEDH:HEPAT)	MEDH: HEPATS	□ (MEDH:HEPATO)
Liver failure (exclude if "yes")	□ (MEDH:LIVERF)	□ (MEDH:LIVERF)	MEDH:LIVERFS	□ (MEDH:LIVERFO)
Chronic endocrine organ problem that requires hormone replacement	□ (MEDH:HORMON)	☐ (MEDH:HORMON)	Specify disorder and hormone treatment: MEDH: HORMONS	□ (MEDH:HORMONC
Endocrine organ failure	□ (MEDH:ENDORG)	□ (MEDH:ENDORG)	MEDH: ENDORGS	□ (MEDH:ENDORGO
Diabetes (exclude if "yes")	□ (MEDH:DIABET)	□ (MEDH:DIABET)	Specify type and treatment: MEDH: DIABETS	□ (MEDH:DIABETO)
Untreated hyperlipidemia (exclude if "yes")	□ (MEDH:HYPERL)	(MEDH:HYPERL)	MEDH: HYPERLS	□ (MEDH:HYPERLO
Chronic renal failure with creatinine > 2 mg/dL (exclude if "yes")	□ (MEDH:RENALF)	□ (MEDH:RENALF)	MEDH:RENALFS	□ (MEDH:RENALFO
Dialysis (exclude if "yes")	□ (MEDH:DIALYS)	□ (MEDH:DIALYS)	MEDH:DIALYSS	□ (MEDH:DIALYSO)
Underlying gastrointestinal disease not related to SCD	□ (MEDH:GASTRO)	□ (MEDH:GASTRO)	Specify disorder: MEDH:GASTROS	□ (MEDH:GASTROO
History of psychiatric medication	□ (MEDH:PSYCMD)	□ (MEDH:PSYCMD)	Specify medication: MEDH: PSYCMDS	□ (MEDH:PSYCMDO
History of psychoses (delusion, hallucination)	□ (MEDH:PSYCHO)	□ (MEDH:PSYCHO)		□ (MEDH:PSYCHOO

(exclude if "yes")			MEDH:PSYCHOS	
Psychiatric disorder resulting in hospitalization for psychoses	□ (MEDH:PSYCDI)	□ (MEDH:PSYCDI)	Specify disorder: MEDH:PSYCDIS	□ (MEDH:PSYCDIO)
Claustrophobia and/or presence of metallic implants such as pacemakers, surgical aneurysm clips, or known metal fragments embedded in the body (exclude if "yes")	□ (MEDH:CLAUST)	□ (MEDH:CLAUST)	MEDH: CLAUSTS	□ (MEDH:CLAUSTO)
	Past H	listory		
Symptom/Event	Yes	No	If "yes", record pertinent comments. Record all date(s) known in the dd/mmm/yy format.	Check if ongoing
Congestive heart failure (exclude if "yes")	□ (MEDH:HEARTF)	□ (MEDH:HEARTF)	MEDH: HEARTFS	□ (MEDH:HEARTFO)
Heart medication	□ (MEDH:HARTMD)	□ (MEDH:HARTMD)	Specify medication and indication: MEDH:HARTMDS	□ (MEDH:HARTMDO)
Coronary artery disease (severe characterized by angioplasty or surgery) (exclude if "yes")	□ (MEDH:CORART)	□ (MEDH:CORART)	Specify treatment: MEDH: CORARTS	□ (MEDH:CORARTO)
Inflammatory arterial disorder (such as lupus or polyarteritis) (exclude if "yes")	□ (MEDH:INFART)	□ (MEDH:INFART)	Specify disorder and treatment: MEDH: INFARTS	□ (MEDH:INFARTO)
Angina (exclude if "yes")	□ (MEDH:ANGINA)	□ (MEDH:ANGINA)	MEDH: ANGINAS	□ (MEDH:ANGINAO)
Arrhythmia	□ (MEDH:ARRHYT)	□ (MEDH:ARRHYT)	MEDH:ARRHYTS	□ (MEDH:ARRHYTO)
Uncontrolled hypertension (exclude if "yes")	□ (MEDH:HYPERT)	□ (MEDH:HYPERT)	MEDH: HYPERTS	□ (MEDH:HYPERTO)
Thrombosis requiring anticoagulant	□ (MEDH:THROMB)	□ (MEDH:THROMB)	Specify anticoagulant: MEDH: THROMBS	□ (MEDH:THROMBO)
Sleep apnea documented by abnormal sleep study	□ (MEDH:APNEA)	□ (MEDH:APNEA)	MEDH: APNEAS	□ (MEDH:APNEAO)
Chronic end-stage lung disease (e.g., characterized by need for oxygen or O ₂ Sat < 90%) (exclude if "yes")	□ (MEDH:LUNGDI)	□ (MEDH:LUNGDI)	MEDH:LUNGDIS	□ (MEDH:LUNGDIO)
Difficulties with breathing	(MEDH:VENTIL)	☐ (MEDH:VENTIL)		□ (MEDH:VENTILO)

Submit Query	Cancel		Form Complet	ion Help Print	x Rho
Comments for page: MEDH:	COMMENT				
If subject is female and has been pregnant: Life-threatening complications of pregnancy	OH:PRGCOM)	□ (MEDH:PRGCOM)	□ (MEDH:PRGCOM)	MEDH: PRGCOMS	□ (MEDH:PRGCOMO)
Avascular Necrosis		□ (MEDH:AVN)	□ (MEDH:AVN)	Specify bone/joint: MEDH: AVNS	□ (MEDH:AVNO)
Acute Chest Syndrom hospitalization	ne requiring	□ (MEDH:ACSHOS)	□ (MEDH:ACSHOS)	Indicate the number of times: ☐ (MEDH:ACSHOSN) 1-4 ☐ (MEDH:ACSHOSN) 5-9 ☐ (MEDH:ACSHOSN) >10 MEDH:ACSHOSS	□ (MEDH:ACSHOSO)
Asthma requiring med	dication	□ (MEDH:ASTHMA)	□ (MEDH:ASTHMA)	Specify medication: MEDH:ASTHMAS	□ (MEDH:ASTHMAO)
				MEDH:VENTILS	

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Intake and Chart Review Neurological

Pilot Transfusion Trial

{visit.label}	Subject ID: Site:

Completion Date:	NEUH:TODAYDA /	NEUH: TODAYMO	/ NEUH:TODAYYR	
	DD	MMM	YYYY	
			ing events and symptoms. For any events marked "Yes", record the onset date of the most rec the exclusion criteria for any events marked "Yes". Indicate if the condition is ongoing by cl	
	Past H	History		
Symptom/Event	Yes	No	If "yes", record pertinent comments. Record all date(s) known in the dd/mmm/yy format.	Check if ongoing
Alteration of level of consciousness	(NEUH:LVLCON)	(NEUH:LVLCON)	NEUH: LVLCONS	(NEUH:LVLCONO)
Two or more headaches per month requiring treatment	(NEUH:HEADAC)	(NEUH:HEADAC)	Severe enough to interfere with functioning? (NEUH:HEADSEV) Yes (NEUH:HEADSEV) No NEUH: HEADACS	(NEUH:HEADACO)
Hemiparesis or othe weakness - Face	er (NEUH:HEMFAC)	(NEUH:HEMFAC)	Specify location : NEUH: HEMFACS	(NEUH:HEMFACO)
Hemiparesis or othe weakness - Arm	er 🔲 (NEUH:HEMARM)	(NEUH:HEMARM)	(NEUH:HEMARMR) Right (NEUH:HEMARML) Left NEUH:HEMARMS	(NEUH:HEMARMO)
Hemiparesis or othe weakness - Leg	er (NEUH:HEMLEG)	(NEUH:HEMLEG)	NEUH: HEMLEGS	(NEUH:HEMLEGO)
Overt stroke (exclude if "yes")	(NEUH:STROKE)	(NEUH:STROKE)	NEUH: STROKES	(NEUH:STROKEO)
Loss of vision	(NEUH:VISION)	(NEUH:VISION)	NEUH:VISIONS	(NEUH:VISIONO)
Alteration of speech	(NEUH:SPEECH)	(NEUH:SPEECH)	NEUH: SPEECHS	(NEUH:SPEECHO)
Clumsiness	(NEUH:CLUMSY)	(NEUH:CLUMSY)	NEUH: CLUMSYS	(NEUH:CLUMSYO)
Seizures	(NEUH:SEIZUR)	(NEUH:SEIZUR)		(NEUH:SEIZURO)

			NEUH:SEIZURS	
Numbness or other	(A)ELILIANIMEAO	(NEUH:NUMFAC)	Specify location :	(NEUH:NUMFACO)
sensory disturbance - Face	(NEUH:NUMFAC)	(NEUH:NUMFAC)	NEUH:NUMFACS	(NEUH:NUMFACO)
Numbness or other	(NEUH:NUMARM)	(NEUH:NUMARM)	(NEUH:NUMARMR) Right (NEUH:NUMARML) Left	(NEUH:NUMARMO)
sensory disturbance - Arm	(,	(,	NEUH: NUMARMS	(
Numbness or other	(NEUH:NUMLEG)	(NEUH-NUMLEG)	(NEUH:NUMLEGR) Right (NEUH:NUMLEGL) Left	(NEUH:NUMLEGO)
sensory disturbance - Leg	III (NEOH.NOWLEG)	(NEOH:NOWLEG)	NEUH: NUMLEGS	(NEOH.NOWLEGO)
Ü				
Abnormal	C (AUELIULIA DALMO) ()	(NEUH:ABNMOV)	NEUH: ABNMOVS	(NEUH:ABNMOVO)
movements (e.g. tremors)	(NEUH:ABNMOV)	(NEUH:ABNMOV)	NEOII · ABINIO VS	(NEUH:ABNMOVO)
Abnormal MRI or CT	_	_		_
	(NEUH:ABNMRI)	(NEUH:ABNMRI)	NEUH: ABNMRIS	(NEUH:ABNMRIO)
(other than small periventricular or				
watershed lesions) (exclude if "yes")				
Neurodegenerative disorders	(NEUH:NEUROD)	(NEUH:NEUROD)	Specify disorder: NEUH: NEURODS	(NEUH:NEURODO)
(exclude if "yes")			NEOR · NEORODS	
Canatia diaandan	_	_		_
Genetic disorder associated with	(NEUH:GENET)	(NEUH:GENET)	Specify disorder: NEUH: GENETS	(NEUH:GENETO)
neurocognitive dysfunction such as				
Down Syndrome (exclude if "yes")				
Head injury resulting	_	_		
in neurological symptoms or	(NEUH:HEADIN)	(NEUH:HEADIN)	NEUH: HEADINS	(NEUH:HEADINO)
medical visit (exclude if "yes")				
(exclude ii yes)				
Comments for pa	nge: NEUH:COMM	ENT		
Comments for pa	ige. International			
	,	_		
Submit Quer	y Cancel		Form Completion Help Print	× Rho

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Focal Neurological Assessment

Pilot Transfusion Trial

{visit.label}
Subject ID:
Site:

Date of Assessr	ment: FOCL: ASSDA / FO	CL:ASSMO / FOCL:ASS	YR			
Level of Consc	ciousness:			Comments		
□ (FOCL:LVL Alert	CON) (FOCL:LVLCON Confused	POORIV	FOCL:LVLCON) of Done	FOCL:LVLCONC		
Tandem Gait:						
□(FOCL:G	GAIT)	•	ot Done	FOCL:GAITC		
Cranial Nerves (III-XII)						
CN III, IV, VI	Normal	Abnormal	Not done			
Pupils	\Box (FOCL:PUPILS)	\Box (FOCL:PUPILS)	☐ (FOCL:PUP	PILS)		
Extra Ocular Movements	□ (FOCL:EXOCUL)	☐ (FOCL:EXOCUL)	□ (FOCL:EXO	CUL)		
Gaze	□ (FOCL:GAZE)	\Box (FOCL:GAZE)	□ (FOCL:GA	ZE)		
CN III, IV, V	'I Comments:					
FOCL: CN3CO	М					
CN V	Normal	Abnormal	Not done	2		
Facial Sensation	□ (FOCL:FACSENS)	\Box (FOCL:FACSENS)	□ (FOCL:FACS	SENS)		
Corneal Reflexes	□ (FOCL:CORNEAL)	□ (FOCL:CORNEAL)	□ (FOCL:CORN	NEAL)		
CN V Comn						
FOCL: CN5CO	М					
CN VII	Normal	Weak	Not done			
Facial Strength	□ (FOCL:FACSTRN)	□ (FOCL:FACSTRN)	□ (FOCL:FACS	STRN)		
Right Lower Face	☐ (FOCL:RLOFACE)	□ (FOCL:RLOFACE)	□ (FOCL:RLOF	FACE)		
Right	□ (FOCL:RUPFACE)	□ (FOCL:RUPFACE)	□ (FOCL:RUPF	FACE)		
Upper Face						
	□ (FOCL:LLOFACE)	☐ (FOCL:LLOFACE)	□ (FOCL:LLOF	ACE)		
Face Left Lower		☐ (FOCL:LUPFACE)	•			

FOCL: CN7CO	М				
CN VIII	Normal	Abnormal	Not done		
Hearing	\Box (FOCL:HEARING)	\Box (FOCL:HEARING)	\Box (FOCL:HEARING)		
CN VIII Con	nments:				
FOCL: CN8CO	М				
CN IX, X	Normal	Abnormal	Not done		
Gag	□ (FOCL:GAG)	□ (FOCL:GAG)	□ (FOCL:GAG)		
Palate Elevation	□ (FOCL:PALATE)	□ (FOCL:PALATE)	□ (FOCL:PALATE)		
CN IX, X Co					
FOCL: CN9CO	М				
CN XI	Normal	Abnormal	Not done		
Trapezius Strength	□ (FOCL:TRAPEZ)	□ (FOCL:TRAPEZ)	□ (FOCL:TRAPEZ)		
CN XI Com					
FOCL: CN11C	OM				
CN XII	Normal	Abnormal	Not done		
Tongue Strength	☐ (FOCL:TONGUE)	☐ (FOCL:TONGUE)	□ (FOCL:TONGUE)		
	Absent	Mild	Moderate	Severe	Not done
Dysarthria	\Box (FOCL:DYSARTH)	\Box (FOCL:DYSARTH)	\Box (FOCL:DYSARTH)	\Box (FOCL:DYSARTH)	☐ (FOCL:DYSARTH
CN XII Com					
FOCL: CN12C	OM				
ther Abnormal	ities, describe:				
FOCL:OTHAI	BND				
ments for page:	FOCL: COMMENT				
	,				
Submit Query	y Cancel	Form C	ompletion Help	Print	x Rho

Physical Exam

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Pilot Transfusion Trial

{visit.label} Subject ID: Site:		
	{visit.label}	•

ate of PHEX: TODAYDA / PHEX	:TODAYMO / PHEX:TODAYYR			
DD	MMM YYYY			
Height (cm): PHEX:HEIGHT	Respirations (RR):	RESPRAT Temperature:	PHEX: TEMP	
/eight (kg): PHEX:WEIGHT	Heart Rate (BPM):	: HEARTRT Units:	(PHEX:TEMPU) °C (PHEX:TEMPU) °F	
Morbid obesity (> 115 kg) is a condition for exclusion		Blood Pressu	PHEX: BPDIA (systolic/diastolic)	
the patient right left handed?)) Right (PHEX:HANDED) Left	(PHEX:HANDED) Ambidex	trous (PHEX:HANDED) Undetermined	
ck the appropriate box for each body system	m/part listed below.		Comments - if a system is "Abnormal" of comments.	or a condition is "Present", be sure to record all pertinent
eral Appearance	(PHEX:GENAPP) Normal	(PHEX:GENAPP) Abnormal	PHEX:GENAPPC	
es	[(PHEX:EYES) Normal	(PHEX:EYES) Abnormal	PHEX: EYESC	
s	(PHEX:EARS) Normal	(PHEX:EARS) Abnormal	PHEX: EARSC	
se/Throat/Mouth	(PHEX:NOSETM) Normal	[(PHEX:NOSETM) Abnormal	PHEX: NOSETMC	
sils [PHEX:TONSIL] Removed	$\[\]$ (PHEX:TONSIL) Not enlarged	(PHEX:TONSIL) Enlarged	PHEX: TONSILC	
id and Neck	(PHEX:HEDNEK) Normal	[(PHEX:HEDNEK) Abnormal	PHEX:HEDNEKC	-
ne	(PHEX:SPINE) Normal	(PHEX:SPINE) Abnormal	PHEX:SPINEC	
st	(PHEX:CHEST) Normal	(PHEX:CHEST) Abnormal	PHEX: CHESTC	
piratory System/Lungs	(PHEX:RESP) Normal	[] (PHEX:RESP) Abnormal	PHEX:RESPC	
gs: Rales	(PHEX:RALES) Absent	(PHEX:RALES) Present	PHEX:RALESC	
gs: Rhonchi	(PHEX:RHONCH) Absent	(PHEX:RHONCH) Present	PHEX:RHONCHC	
gs: Wheezing	[(PHEX:WHEEZ) Absent	(PHEX:WHEEZ) Present	PHEX:WHEEZC	
gs: Mouth Breathing	[] (PHEX:MOUTHB) Absent	(PHEX:MOUTHB) Present	PHEX:MOUTHBC	
diovascular System	[(PHEX:CARDIO) Normal	[(PHEX:CARDIO) Abnormal	PHEX:CARDIOC	
art: Rhythm Abnormality	[(PHEX:RHYABN) Absent	\square (PHEX:RHYABN) Present	PHEX:RHYABNC	
art: Murmur	(PHEX:MURMUR) Absent	(PHEX:MURMUR) Present	PHEX:MURMURC	

Version: 18 Feb 2009

			PHEX: ABDOMNC	
Spleen	(PHEX:SPLEEN) Not enlarged	(PHEX:SPLEEN) Enlarged	Measure distance below left mid-costa	al margin in cm:
			PHEX:SPLEENC	
Liver	\square (PHEX:LIVER) Not enlarged	(PHEX:LIVER) Enlarged	Measure distance below right mid-cos	
			PHEX:LIVERC	
Liver: Tenderness	[PHEX:LIVTND] Absent	(PHEX:LIVTND) Present	PHEX:LIVTNDC	
Lymph Nodes	(PHEX:LYMPH) Not enlarged	(PHEX:LYMPH) Enlarged	PHEX:LYMPHC	
Dermatological System	(PHEX:DERMAT) Normal	(PHEX:DERMAT) Abnormal	PHEX: DERMATC	
Genitourinary System	(PHEX:GENITO) Normal	[(PHEX:GENITO) Abnormal	PHEX:GENITOC	
Musculoskeletal System	(PHEX:MUSCUL) Normal	(PHEX:MUSCUL) Abnormal	PHEX:MUSCULC	
	_	_		
Motor weakness of extremities	(PHEX:MOTOR) Absent	(PHEX:MOTOR) Present	Check all extremities with motor weakned	Left Arm
			(PHEX:MOTORRA) (PHEX:MOTORRA) Right Leg	(PHEX:MOTORLL) Left Leg
			Weakness is: (check only one)	(PHEX:WEAKNES) Neurological (PHEX:WEAKNES) Secondary to musculoskeletal damage
			PHEX:MOTORC	
Sensory weakness of extremities	(PHEX:SENSO) Absent	(PHEX:SENSO) Present	Check all extremities with sensory weak	ness:
				SENSOLA) Left Arm HEX:SENSOLL) Left Leg
			PHEX: SENSOC	
Pain or limitation of range of motion in hip	(PHEX:PAIN) Absent	(PHEX:PAIN) Present	PHEX:PAINC	
Leg ulcer	(PHEX:LEGULC) Absent	(PHEX:LEGULC) Present	PHEX:LEGULCC	
Lower extremity edema	(PHEX:EDEMA) Absent	(PHEX:EDEMA) Present	PHEX: EDEMAC	
Comments for page: PHEX:COMMENT				
Submit Query Cancel		Form Cor	mpletion Help	Print X Rho
Canoci		55.		

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Alcohol and Non-Rx Drug Use

Pilot Transfusion Trial

{visit.label}

Subject ID:
Site:

Completion Date : DRUG	G:TODAYDA / DRUG:TODAYMO	/ DRUG:TODAYYR		
,	DD MMM	YYYY		
average for use of	ding <i>current</i> use of the follo f the following substances "N/A" for a particular subs	within the most s	suitable time pe	eriod (i.e., # drinks o
Total alcohol consumption	Alcohol	N/A	# drinks	per
exceeding 14 drinks/week for women and 21	Beer	(DRUG:BEERNA)	DRUG: BEER	DRUG:BEERTP
drinks/week for men requires exclusion	Wine	(DRUG:WINENA)	DRUG: WINE	DRUG:WINETP _
from the study.	Other alcoholic drinks	(DRUG:OTALCNA)	DRUG:OTALC	DRUG: OTALCTP _
Current drug abuse (use of	Non-Rx Drug Use	N/A	# times	per
non-prescribed medication) or habitual marijuana use requires exclusion from the study. Exclude subject if he/she is a habitual	Habitual marijuana use (hashish or hash oil). Habitual use is defined as > 20 joints/week for more than one week in the last month.	(DRUG:MARIJNA)	DRUG:MARIJ 1	DRUG:MARIJTP ▼
marijuana user or currently uses any	Cocaine/Crack	(DRUG:CRACKNA)	DRUG: CRACK	DRUG: CRACKTP 🔻
of the other drugs listed.	Inhalants (glue, fumes, amyls)	(DRUG:INHALNA)	DRUG: INHAL	DRUG: INHALTP
	Amphetamines (uppers)	(DRUG:AMPHNA)	DRUG: AMPH	DRUG: AMPHTP
	Non-prescribed Ritalin	(DRUG:RITALNA)	DRUG:RITAL 1	DRUG:RITALTP 🔻
	Methcathinone (cat)	(DRUG:MTHCANA)	DRUG: MTHCA	DRUG: MTHCATP 🔻
	Non-prescribed tranquilizers	(DRUG:TRANQNA)	DRUG: TRANQ	DRUG:TRANQTP 🔻

	Non-prescribed narcotics (opium, morphine, codeine, vicodin)	(DRUG:NARCONA)	DRUG: NARCO	DRUG:NARCOTP	
	Heroin	(DRUG:HEROINA)	DRUG:HEROI	DRUG: HEROITP	
	LSD (acid)	(DRUG:LSDNA)	DRUG: LSD	DRUG:LSDTP 🔻	
	MDMA (ecstasy, XTC, X)	(DRUG:MDMANA)	DRUG: MDMA	DRUG:MDMATP	
	Other psychedelics (psilocybin, mescaline, etc.)	(DRUG:PSYCHNA)	DRUG: PSYCH	DRUG: PSYCHTP	
	Other: DRUG: OTDRGS	(DRUG:OTDRGNA)	DRUG: OTDRG	DRUG:OTDRGTP	1
Comments for page:	DRUG: COMMENT				
Submit Query	Cancel	Form Completion	Help	Print	× Rho

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

WAIS-III PIQ Pilot Transfusion Trial

(visit.label)

Subject ID: Site:

Date of Assessment: WAI2:ASSDA / WAI2:ASSMO / WAI2:ASSYR MMM Enter <, >, <=, >=, and % as necessary. **Age-Adjusted Scaled Scores** Reference Group **SUBTESTS** Raw Score VERBAL PERF. VC РО WM PS **Scaled Scores** WAI2:PERFA Picture WAI2:RAWA WAI2:POA WAI2:SCALEA1 Completion Digit Symbol-WAI2:RAWC WAI2:PERFC WAI2:PSC WAI2:SCALEC1 Coding Block Design WAI2:RAWE WAI2:PERFE WAI2:POE WAI2:SCALEE1 Matrix-WAI2:RAWG WAI2:PERFG WAI2:POG WAI2:SCALEG1 Reasoning Picture WAI2:RAWJ WAI2:PERFJ WAI2:SCALEJ1 Arrangement Symbol Search WAI2:RAWL (WAI2:PERFL) WAI2:PSL WAI2:SCALEL1 Object WAI2:RAWN (WAI2:PERFN) WAI2:SCALEN1 Assembly Sums of WAI2:VERBS WAI2:PERFS WAI2:VCS WAI2:POS WAI2:WMS WAI2:PSS Scaled Scores VERBAL PERF. vc РΟ WM PS × × Full Scale Score (Verbal + WAI2:FULLSS Performance) × IQ/INDEX VIQ PIQ **FSIQ** VCI POI WMI PSI **SCORES** Sums of WAI2:VIQSUM WAI2:PIQSUM WAI2:FSIQSUM WAI2:VCISUM WAI2:POISUM WAI2:WMISUM WAI2:PSISUM Scaled Scores WAI2:VCIIND WAI2:POIIND WAI2:PSIIND IQ/Index Score WAI2:VIQIND WAI2:PIQIND WAI2:FSIQIND WAI2:WMIIND Percentiles WAI2:VIQPCT WAI2:PIQPCT WAI2:FSIQPCT WAI2:VCIPCT WAI2:POIPCT WAI2:WMIPCT WAI2:PSIPCT Confidence WAI2:VIQCON WAI2:PIQCON WAI2:FSIQCON WAI2:VCICON WAI2:POICON WAI2:WMICON WAI2:PSICON Intervals Enter all confidence WAI2:CONFINT intervals as a range X-Y Comments for page: WAI2:COMMENT Submit Query Cancel Print

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Inclusion Criteria

Pilot Transfusion Trial

{visit.label}

Subject ID: Site:

Col	mpletion Date:	INCS:TODAYDA / INC	CS:TODAYN	10 / INCS:TODAYY	R
		DD	MMM	YYYY	
For t	he subject to be co	onsidered eligible for this st	udy, Questic	ons 1 through 9 must be	e answered Yes.
1.	Is the subject and 55?	an adult between the	ages of	□ (INCS:INCL1) Yes	□ (INCS:INCL1) No
2.	Is the subject	of African descent?		□ (INCS:INCL2) Yes	□ (INCS:INCL2) No
3.	language?	proficient/fluent in the not have to be the su		□ (INCS:INCL3) Yes	□ (INCS:INCL3) No
4.	•	oin electrophoresis co S or SB ⁰ been perfor	_	□ (INCS:INCL4) Yes	□ (INCS:INCL4) No
5.	Is the subject's	s hemoglobin A < 15%	%?	□ (INCS:INCL5) Yes	□ (INCS:INCL5) No
6.	Is the subject's	s hemoglobin ≤ 9.0 g/	dL?	□ (INCS:INCL6) Yes	□ (INCS:INCL6) No
7.		wing been completed nysical Exam, MMSE		□ (INCS:INCL7) Yes	□ (INCS:INCL7) No
8.	Is the subject's	s WAIS III PIQ score	≤ 90?	☐ (INCS:INCL8) Yes	□ (INCS:INCL8) No
9.	Is the subject	capable of giving			

informed consent for the protocol? [INCS:INCL9) Yes [INCS:INCL9) No

If yes, date of informed consent: INCS:INFCDA / INCS:INFCMO / INCS:INFCYR

DD MMM YYYY

Comments for page: INCS:COMMENT

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Neuropsychological
Dysfunction and
Neuroimaging
Abnormalities in
Neurologically Intact
Adult Patients With
Sickle Cell Disease

Exclusion Criteria

Pilot Transfusion Trial

{visit.label}

Subject ID:

Site:

Com	pletion Date: EXCS:TODAYDA / EXCS:TODAYMO / N	EXCS: TODAYYR							
	DD MMM	YYYY							
	For the subject to be considered eligible for this study, Questions 1 through 27 must be answered No. Question 10 may be N/A.								
1.	Has the subject ever suffered from an overt stroke?	(EXCS:EXCL1) Yes	(EXCS:EXCL1)						
2.	Is there previous evidence of an abnormal MRI or CT other than small periventricular or watershed lesions?	(EXCS:EXCL2) Yes	(EXCS:EXCL2)						
3.	Does the subject have a history of head injury that resulted in neurological symptoms or a medical visit?	(EXCS:EXCL3) Yes	(EXCS:EXCL3)						
4.	Has the subject had an abnormal neurological exam with focal findings?	(EXCS:EXCL4) Yes	(EXCS:EXCL4)						
5.	Does the subject have a Mini-Mental Status Examination (MMSE) score of < 20?	(EXCS:EXCL5) Yes	(EXCS:EXCL5)						
6.	Is the subject's Profile of Mood States (POMS) Depression/Dejection subscale score > 40?	(EXCS:EXCL6) Yes	(EXCS:EXCL6)						
7.	Does the subject's alcohol consumption exceed 14 drinks/week if female or 21 drinks/week if male?	(EXCS:EXCL7) Yes	(EXCS:EXCL7)						
8.	Does the patient have a history of drug abuse defined as using non-prescribed medication?	(EXCS:EXCL8) Yes	(EXCS:EXCL8)						

9.	Does the subject have a histoclaustrophobia, and/or prese implants such as pacemaker clips, or known metal fragme body?	nce of metallic s, surgical aneurys		(EXCS:EXCL9)	
10.		(EXCS:EXCL10) Not Applicable	(EXCS:EXCL10) Yes	(EXCS:EXCL10)	
11.	Is the subject currently on ch therapy?	nronic transfusion	(EXCS:EXCL11) Yes	(EXCS:EXCL11)	
12.	Does the subject have a bas pressure of > 140/90 on two measurements?		(EXCS:EXCL12) (EXCS:EXCL12) Yes No		
	(A second measurement if the first is > 1				
13.	Does the subject have a hist uncontrolled hypertension?	tory of	(EXCS:EXCL13) Yes	(EXCS:EXCL13)	
14.	Does the subject have any comay result in neurocognitive that is not secondary to Sic including but not limited to:	or brain dysfunctio		14) (EXCS:EXCL14) No	
	 a. Inflammatory arterial depolyarteritis) b. History of cancer requisand/or radiation c. Untreated hyperlipident d. Diabetes e. Ongoing active infection tuberculosis, sarcoidost f. Chronic renal failure g. Any condition requiring h. Chronic lung disease of for oxygen i. Morbid obesity (weight j. Heart disease: history failure, history of sever disease characterized surgery, or history of a k. Active hepatitis or liver l. Acquired or congenital m. Neurodegenerative dis 	ring chemotherapy nia on such as HIV, sis g dialysis characterized by new greater than 115 k of congestive heart re coronary artery by angioplasty or ngina failure immune deficiency	g)		

n. Genetic disorder associated with

Syndrome o. History of psychoses and/or schizophrenia 15. In the investigator's opinion, is there any other chronic illness or disorder **other than SCD** that (EXCS:EXCL15) (EXCS:EXCL15) will adversely affect the subject's performance in Yes this study? 16. Is the subject currently on Procrit or a related drug that stimulates red blood cell production? (EXCS:EXCL16) (EXCS:EXCL16) Yes No 17. Does the subject have a history of life threatening or serious transfusion complications? (EXCS:EXCL17) (EXCS:EXCL17) Yes No 18. Does the subject have a lack of venous access? (EXCS:EXCL18) (EXCS:EXCL18) Yes No 19. Does the subject refuse transfusion? (EXCS:EXCL19) (EXCS:EXCL19) 20. Does the subject have a history of unexplained severe hemolytic transfusion (EXCS:EXCL20) (EXCS:EXCL20) reaction? Yes 21. Does the subject have a history of serious allergic, pulmonary transfusion reaction requiring (EXCS:EXCL21) (EXCS:EXCL21) hospitalization for the reaction? Yes 22. Does the subject have positive auto-immune hemolytic anemia (direct coombs with IGG (EXCS:EXCL22) (EXCS:EXCL22) and complement)? Yes No 23. Does the subject have multiple (3 or more) clinically significant allo-antibodies, due to (EXCS:EXCL23) (EXCS:EXCL23) common antigens (for example: EC, Kel)? No 24. Does the subject have an uncommon, clinically significant antibody that results in (EXCS:EXCL24) (EXCS:EXCL24) difficulty finding matched units (for example: No Yes anti-JKB)? 25. Is the subject taking Hydroxyurea and not on a stable dose for \geq 6 months? (EXCS:EXCL25) (EXCS:EXCL25)

neurocognitive dysfunction such as Down

26. Does the subject have a creatinine level > 1.7? (EXCS:EXCL26) (EXCS:EXCL26) Yes No 27. Does the subject have a ferritin level > 1,500 ng/mL or quantitative liver iron > 7 mg iron/g dry (EXCS:EXCL27) (EXCS:EXCL27) weight and not currently on iron chelation Yes therapy? Has the subject met all eligibility requirements? ☐ (EXCS:ELIGYN) Yes ☐ (EXCS:ELIGYN) No If yes (subject is eligible), has the subject been enrolled in the study? ☐ (EXCS:ENROLYN) Yes ☐ (EXCS:ENROLYN) No If no (subject IS eligible and is NOT enrolled), give reason not enrolled: EXCS:REASON Comments for page: EXCS: COMMENT Cancel Form Completion Help × Rho Submit Query Print

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

External MRI Data

Pilot Transfusion Trial

{visit.lab	el}
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Subject ID: Site:

Date of procedure: MRIT: PROCDA / MRIT: PROCMO / MRIT: PROCYR Technologist Initials
DD MMM YYYY
Was the MRI performed according to the required imaging sequences as specified in the protocol? ☐ (MRIT:MRIPROT) Yes ☐ (MRIT:MRIPROT) No
Did the subject cooperate fully for the procedure? ☐ (MRIT:COOP) Yes ☐ (MRIT:COOP) No
If No, explain: MRIT: COOPEX
Did the subject require sedation for the MRI? ☐ (MRIT:SEDYN) Yes ☐ (MRIT:SEDYN) No
If Yes, name of medication(s): MRIT: SEDMED
What type of shim was used before scanning? MRIT: SHIM
Sagittal 2D
Was there any table movement between sequences? ☐ (MRIT:SAGTABL) Yes ☐ (MRIT:SAGTABL) No
If Yes, how much? MRIT: SAGCM cm
Was there any noticeable movement or other degradation on images? ☐ (MRIT:SAGMOVE) Yes ☐ (MRIT:SAGMOVE) No
If Yes, explain: MRIT: SAGEXP
Was there full head coverage? ☐ (MRIT:SAGHEAD) Yes ☐ (MRIT:SAGHEAD) No
3D T1 MPRage/SPGR □ (MRIT:MPRAGE) Yes □ (MRIT:MPRAGE) No Acquisition Number □ MRIT:MPRACQ
☐ (MRIT:PERPANG)Check here if perpendicular to Angle of Hippocampus
Was there any table movement between sequences? ☐ (MRIT:MPRTABL) Yes ☐ (MRIT:MPRTABL) No
If Yes, how much? MRIT: MPRCM cm
Was there any noticeable movement or other degradation on images? ☐ (MRIT:MPRMOVE) Yes ☐ (MRIT:MPRMOVE) No
If Yes, explain: MRIT: MPREXP
Was there full head coverage? ☐ (MRIT:MPRHEAD) Yes ☐ (MRIT:MPRHEAD) No
Axial PD/T2 2D spin- echo
☐ (MRIT:PARALEL)Check here if parallel to AC-PC line
Was there any table movement between sequences? \Box (MRIT:AXITABL) Yes \Box (MRIT:AXITABL) No
If Yes, how much? MRIT: AXICM cm
Was there any noticeable movement or other degradation on images?

If Yes, explain. MRIT: AXIEXP
If Yes, explain: MRIT: AXIEXP
Was there full head coverage? ☐ (MRIT:AXIHEAD) Yes ☐ (MRIT:AXIHEAD) No
Has the scan
If No, explain: MRIT: ARCHEXP
Type of media used for archiving: Optical (MRIT:MEDIA) DAT Tape (MRIT:MEDIA) Disk Optical (MRIT:MEDIA) Other: MRIT:MEDIAOT
Date MRI sent to UCSF VA MRIT:UCSFDA / MRIT:UCSFMO / MRIT:UCSFYR FedEx Tracking# MRIT:FEDEX for analysis: DD MMM YYYY
Comments for page: MRIT:COMMENT
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Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Neurocognitive Battery

Pilot Transfusion Trial

Patients With Sickle Cell Disease							
	{visit.label}	Subject ID: Site:					
This form must be completed before any tests in the Neuropsych Battery are administered on any given day. This form only needs to be completed once for any day on which a group of tests is administered, but if the NP Battery is divided over more than one day then the questions must be repeated before the start of testing for the remaining tests. Click the [Add testing day] button in order to enter observational data for each day on which neuropsychological instruments are to be administered. If any of the questions are answered "Yes" then also elaborate in the comments field at the bottom of the page (include attempted date of testing) and reschedule neuropsychological testing for another day.							
	TESTMO / BTOB:TESTYR MM YYYY						
Is the subject under the influence of any non medication that may affect his or her perforn tests (i.e., pain medication such as opiates)?	nance on any of these	(BTOB:BATOBS1) No					
In the last 24 hours, has the subject taken at known to impair neurocognitive performance intravenous drugs, non-prescribed narcotics	e (i.e., alcohol, marijuana,	Remove Remove					
Does the subject seem inattentive or sedate off, disinterested, having trouble concentration.	(BIOB:BAIOBS3) Yes	BTOB:BATOBS3) No					
Add testing day Comments: BTCM:COMMENT							
Submit Query Cancel	Form Completion Help	Print Rho					

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Woodcock-Johnson III

Pilot Transfusion Trial

Cickie Con Diocase		
	{visit.label}	Subject ID: Site:

Date of Assessment:	R3:ASSDA / WJR3:ASSMO / WJR3:ASSYR DD MMM YYYY
Does the subject have glass	ees? (WJR3:GLASSES) Yes (WJR3:GLASSES) No
Were they used duri	ing testing?
Does the subject have a hea	aring aid? (WJR3:HEARAID) Yes (WJR3:HEARAID) No
Was it used during t	testing?
Other Information:	
WJR3:OTHINFO	
Test Session Observ	vations Checklist
Check only one category fo	or each item
Level of conversational profi	iciency
(WJR3:CONPROF)	1. Very advanced
(WJR3:CONPROF)	2. Advanced
(WJR3:CONPROF)	3. Typical for age/grade
(WJR3:CONPROF)	4. Limited
(WJR3:CONPROF)	5. Very limited
Level of cooperation	
(WJR3:COOPER)	1. Exceptionally cooperative throughout the examination
(WJR3:COOPER)	2. Cooperative (typical for age/grade)
(WJR3:COOPER)	3. Uncooperative at times
(WJR3:COOPER)	4. Uncooperative throughout the examination
Level of activity	
(WJR3:ACTIVE)	1. Seemed lethargic
(WJR3:ACTIVE)	2. Typical for age/grade
(WJR3:ACTIVE)	3. Appeared fidgety or restless at times
(WJR3:ACTIVE)	4. Overly active for age/grade; resulted in difficulty attending to tasks

Attention and deoperation					
(WJR3:ATTENT)	1. Unusually absorbed by the tasks				
(WJR3:ATTENT)	2. Attentive to the tasks				
(WJR3:ATTENT)	3. Distracted often				
(WJR3:ATTENT)	4. Consistently inattentive and distracted				
Self-confidence					
(WJR3:SELFCON)	1. Appeared confident and self-assured				
(WJR3:SELFCON)	2. Appeared at ease and comfortable (typical	l for age/grade)			
(WJR3:SELFCON)	3. Appeared tense or worried at times				
(WJR3:SELFCON)	4. Appeared overtly anxious				
Care in responding					
(WJR3:CARERES)	1. Very slow and hesitant in responding				
(WJR3:CARERES)	2. Slow and careful in responding				
(WJR3:CARERES)	3. Prompt but careful in responding (typical	l for age/grade)			
(WJR3:CARERES)	4. At times responded too quickly				
(WJR3:CARERES)	5. Impulsive and careless in responding				
Response to difficult tasks					
(WJR3:DIFTASK)	1. Noticeably increased level of effort for	difficult tasks			
(WJR3:DIFTASK)	2. Generally persisted with difficult tasks	(typical for age/grade)			
(WJR3:DIFTASK)	3. Attempted but gave up easily				
(WJR3:DIFTASK)	4. Would not try difficult tasks at all				
			П		
Do you have any reason to	believe that this testing session may not represent a fair sam	pple of the subject's abilities?	(WJR3:NOTFAIR)		
The re	esults may not be a fair estimate because	WJR3:NOFAIRS			
Yes					
			_		
Were any modifications ma	de to the standard testing procedures during this administration	on?	(WJR3:MODSYN)		
□ The fr	ollowing modifications were made:	WITH A MODER	No		
(WJR3:MODSYN)	nowing modifications were made.	WJR3:MODSS			
Yes					

	Number Correct	Number Incorrect	Total Points	AE	GE
Test 1: Letter-Word Identification	WJR3:T1NCOR			WJR3:T1AE	WJR3:T1GE
Test 2: Reading Fluency	WJR3:T2NCOR	WJR3:T2NOINC	WJR3:T2TOTPT	WJR3:T2AE	WJR3:T2GE

NOTE: Enter AE and GE scores exactly as they appear in the testing manual.

Test 4: Understanding D	irections					
Scoring is based on the administration of specific groups of pictures.			admin correspo picture continuati	an one group of picture istered, use the colun onding to the last grou is administered followi on instructions. Enter not administered.	n p of ng	
Picture 1	WJR3:T4P1		Picture 1	WJR3:T4P_1		
Picture 2	WJR3:T4P2	×	Pictures	WJR3:T4P23	AE	WJR3:T4AE
Picture 3	WJR3:T4P3		2-3	WUR3:14P23		
Picture 4	WJR3:T4P4	×	Pictures	WJR3:T4P45		
Picture 5	WJR3:T4P5		4-5	MORES - 1 1 F 1 5	GE	WJR3:T4GE
Picture 6	WJR3:T4P6		Picture 6	WJR3:T4P_6		

	Number Correct	AE	GE
Test 5: Calculation	WJR3:T5NCOR	WJR3:T5AE	WJR3:T5GE
Test 6: Math Fluency	WJR3:T6NCOR	WJR3:T6AE	WJR3:T6GE
Test 7: Spelling	WJR3:T7NCOR	WJR3:T7AE	WJR3:T7GE
Test 9: Passage Comprehension	WJR3:T9NCOR	WJR3:T9AE	WJR3:T9GE
Test 10: Applied Problems	WJR3:T10NCOR	WJR3:T10AE	WJR3:T10GE

Comments for page: WJR3:COMMENT

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Neuropsychological **Dysfunction and Neuroimaging** Abnormalities in **Neurologically Intact Adult Patients With Sickle Cell Disease**

Delis-Kaplan Executive Functioning System

Pilot Transfusion Trial

Date	of	Assessmen	ıt
Date	•	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	

DKAP:ASSDA / DKAP:ASSMO / DKAP:ASSYR DD

MMM

YYYY

{visit.label}

Subject ID: Site:

Trail Making Test

Primary Measure: Completion Times

	Raw Score	Scaled Score
Condition 1: Visual Scanning	DKAP:TMCON1R	DKAP:TMCON1S
Condition 2: Number Sequencing	DKAP:TMCON2R	DKAP:TMCON2S
Condition 3: Letter Sequencing	DKAP: TMCON3R	DKAP:TMCON3S
Condition 4: Number-Letter Switching	DKAP:TMCON4R	DKAP:TMCON4S
Condition 5: Motor Speed	DKAP:TMCON5R	DKAP:TMCON5S

Primary Combined Measure: Completion Times

	Sum of Scaled Scores	Composite Scaled Score
Combined Number + Letter Sequencing	DKAP: TMSUMS	DKAP: TMCOMPS

Primary Contrast Measures: Completion Times

	Scaled Score Difference	Contrast Scaled Score *
Switching vs. Visual Scanning	DKAP:TMSCLDA	DKAP: TMCONTA
Switching vs. Number Sequencing	DKAP:TMSCLDB	DKAP: TMCONTB
Switching vs. Letter Sequencing	DKAP:TMSCLDC	DKAP: TMCONTC
Switching vs. Combined Number + Letter Sequencing	DKAP: TMSCLDD	DKAP: TMCONTD
Switching vs. Motor Speed	DKAP:TMSCLDE	DKAP: TMCONTE
the second secon		

^{*} A low or high contrast scaled score may reflect different cognitive problems; see examiner's manual.

Optional Measures: Error Analysis

	Raw Score	Cumulative %ile Rank
Omission Errors: Condition 1 (Visual Scanning)	DKAP:TMC10ER	DKAP:TMC10EC
Commission Errors: Condition 1 (Visual Scanning)	DKAP: TMC1CER	DKAP: TMC1CEC
Sequencing Errors: Condition 2 (Number Sequencing)	DKAP:TMC2SER	DKAP:TMC2SEC
Sequencing Errors: Condition 3 (Letter Sequencing)	DKAP:TMC3SER	DKAP:TMC3SEC
Sequencing Errors: Condition 4 (Number-Letter Switching)	DKAP:TMC4SER	DKAP:TMC4SEC

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Set-Loss Errors Condition 2 (Number Sequencing)	DKAP:TMC2SLR	DKAP:TMC2SLC
Set-Loss Errors Condition 3 (Letter Sequencing)	DKAP:TMC3SLR	DKAP:TMC3SLC
Set-Loss Errors Condition 4 (Number-Letter Switching)	DKAP:TMC4SLR	DKAP:TMC4SLC
Time Discontinue Errors: Condition 2 (Number Sequencing)	DKAP:TMC2TDR	DKAP:TMC2TDC
Time Discontinue Errors: Condition 3 (Letter Sequencing)	DKAP:TMC3TDR	DKAP:TMC3TDC
Time Discontinue Errors: Condition 4 (Number-Letter Switching)	DKAP:TMC4TDR	DKAP:TMC4TDC
Time Discontinue Errors: Condition 5 (Motor Speed)	DKAP:TMC5TDR	DKAP:TMC5TDC
All Error Types: Condition 4 (Number-Letter Switching)	DKAP:TMC4RAW	DKAP:TMC4SCL

* Scaled Score

Verbal Fluency Test

Primary Measures

	Raw Score	Scaled Score
Letter Fluency: Total Correct	DKAP:VFCON1R	DKAP:VFCON1S
Category Fluency: Total Correct	DKAP: VFCON2R	DKAP: VFCON2S
Category Switching: Total Correct Responses	DKAP:VFCN3AR	DKAP: VFCN3AS
Category Switching: Total Switching Accuracy	DKAP:VFCN3BR	DKAP: VFCN3BS

Primary Contrast Measures

	Scaled Score Contrast Scaled Difference Score *
Letter Fluency vs. Category Fluency	DKAP:VFLFCF3 DKAP:VFLFCF4
Category Switching vs. Category Fluency	DKAP:VFCSCF3 DKAP:VFCSCF4

^{*} A low or high contrast scaled score may reflect different cognitive problems; see examiner's manual.

Optional Measures: Conditions 1-3 Combined

	Letter Fluency Raw Score	Category Fluency Raw Score	Category Switching Raw Score	Total Raw Score	Scaled Score
First Interval: Total Correct	DKAP:VFC1R1	DKAP:VFC2R1	DKAP:VFC3R1	DKAP:VFTOTR1	DKAP:VFSCLS1
Second Interval: Total Correct	DKAP:VFC1R2	DKAP:VFC2R2	DKAP:VFC3R2	DKAP:VFTOTR2	DKAP:VFSCLS2
Third Interval: Total Correct	DKAP:VFC1R3	DKAP:VFC2R3	DKAP:VFC3R3	DKAP: VFTOTR3	DKAP: VFSCLS3
Fourth Interval: Total Correct	DKAP:VFC1R4	DKAP:VFC2R4	DKAP:VFC3R4	DKAP:VFTOTR4	DKAP:VFSCLS4
Set-Loss Errors	DKAP:VFC1R5	DKAP:VFC2R5	DKAP:VFC3R5	DKAP: VFTOTR5	DKAP: VFSCLS5
Repetition Errors	DKAP:VFC1R6	DKAP:VFC2R6	DKAP:VFC3R6	DKAP: VFTOTR6	DKAP:VFSCLS6
Total Responses (Correct+Incorrect) *	DKAP:VFC1R7	DKAP:VFC2R7	DKAP:VFC3R7	DKAP:VFTOTR7	

*Note: Some repetition Errors are coded also as Set-Loss Errors; each double-coded error counts only as one response for the Total Responses Measure.

	Score	Scaled Score
Percent Set-Loss Errors	DKAP:VFPSLE3	DKAP:VFPSLE4
Percent Repetition Errors	DKAP: VFPRE3	DKAP:VFPRE4
Category Switching: Percent Switching Accuracy	DKAP: VFPCTR	DKAP: VFSCALE

Color-Wo	ord I	nterfer	ence	Test
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Primary Measures: Completion Times

	Raw Score	Scaled Score
Condition 1: Color Naming	DKAP: CWCON1R	DKAP: CWCON1S
Condition 2: Word Reading	DKAP: CWCON2R	DKAP: CWCON2S
Condition 3: Inhibition	DKAP: CWCON3R	DKAP: CWCON3S
Condition 4: Inhibition / Switching	DKAP: CWCON4R	DKAP: CWCON4S

Primary Combined Measure: Completion Times

	Sum of Scaled Scores	Composite Scaled Score
Combined Naming + Reading	DKAP: CWSUMS	DKAP: CWCOMPS

Primary Contrast Measures: Completion Times

	Scaled Score Difference	Contrast Scaled Score *
Inhibition vs. Color Naming	DKAP: CWSCLDA	DKAP: CWCONTA
Inhibition/Switching vs. Combined Naming+Reading	DKAP: CWSCLDB	DKAP: CWCONTB
Inhibition/Switching vs. Inhibition	DKAP: CWSCLDC	DKAP: CWCONTC

^{*} A low or high contrast scaled score may reflect different cognitive problems; see examiner's manual.

Optional Contrast Measures: Completion Times

	Scaled Score Difference	Contrast Scaled Score *
Inhibition/Switching vs. Color Naming	DKAP: CWSCLDD	DKAP: CWCONTD
Inhibition/Switching vs. Word Reading	DKAP: CWSCLDE	DKAP: CWCONTE

^{*} A low or high contrast scaled score may reflect different cognitive problems; see examiner's manual.

Optional Measures: Error Analysis

	Cor. Errors Raw Score	Cor. Errors Cum. Freq. Rank	Uncor. Errors Raw Score	Uncor. Errors Cum. Freq. Rank	Total Errors Raw Score	Total Errors Scaled Score
Cond 1: Color Naming	DKAP: CWC1CER		DKAP: CWC1UER		DKAP: CWC1TER	DKAP:CWC1TEC
Cond 2: Word Reading	DKAP: CWC2CER		DKAP: CWC2UER		DKAP: CWC2TER	DKAP:CWC2TEC
Cond 3: Inhibition	DKAP: CWC3CER	DKAP: CWC3CEC	DKAP: CWC3UER	DKAP: CWC3UEC	DKAP: CWC3TER	DKAP:CWC3TES

Cond 4:

*Cumulative Percentile Rank

Twenty Questions Test							
Primary Measures							
	Item 1 Raw Score	Item 2 Raw Score	Item 3 Raw Score	Item 4 Raw Score	Total Raw Score	Scaled Score	
Initial Abstraction Score *	DKAP:TQI1RA	DKAP:TQI2RA	DKAP:TQI3RA	DKAP:TQI4RA	DKAP:TQTOTRA	DKAP: TQSCLA	
* M	inimum number of	objects that can be	e eliminated by the	first question aske	ed regardless of the	yes or no answe	
Total Questions Asked	DKAP:TQI1RB	DKAP:TQI2RB	DKAP:TQI3RB	DKAP:TQI4RB	DKAP:TQTOTRB	DKAP: TQSCLE	
Total Weighted Achievement Score	DKAP:TQI1RC	DKAP:TQI2RC	DKAP:TQI3RC	DKAP:TQI4RC	DKAP:TQTOTRC	DKAP: TQSCLO	
Optional Measures							
	Item 1 Raw Score	Item 2 Raw Score	Item 3 Raw Score	Item 4 Raw Score	Total Raw Score	Cum. %ile Rank	
Spatial Questions	DKAP:TQI1RD	DKAP:TQI2RD	DKAP:TQI3RD	DKAP:TQI4RD	DKAP:TQTOTRD	DKAP: TQCPRI	
Repeated Questions	DKAP:TQI1RE	DKAP:TQI2RE	DKAP:TQI3RE	DKAP:TQI4RE	DKAP:TQTOTRE	DKAP: TQCPRI	
Set-Loss Questions	DKAP:TQI1RF	DKAP:TQI2RF	DKAP:TQI3RF	DKAP:TQI4RF	DKAP:TQTOTRF	DKAP: TQCPRE	

Tower Test	
Primary Measure	
Total Raw Score Scaled Score	
Total Achievement Score DKAP:TTACHVR DKAP:TTACHVS	
Optional Measures	
	Total Raw Score Cum. %ile Rank
Total Rule Violations	DKAP:TTRULE1 DKAP:TTRULE4
	Ratio Score Scaled Score
Mean First-Move Time *	DKAP: TTMEAN3 DKAP: TTMEAN4
Time-Per-Move-Ratio *	DKAP:TTTPMR3 DKAP:TTTPMR4
Move Accuracy Ratio *	DKAP:TTACCR3 DKAP:TTACCR4
Rule-Violations-Per-Item-Ratio	DKAP:TTRVR3 DKAP:TTRVR4

Comments for Page: DKAP: COMMENT

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Neuropsychological Dysfunction and Neuroimaging Abnormalities in **Neurologically Intact Adult Patients** With Sickle Cell Disease

Wisconsin Card Sorting Test

Pilot Transfusion Trial

{visit.label}

Subject ID:

Site:

Date of Assessment: WCST:ASSDA / WCST:ASSMO / WCST:ASSYR

SCORING AREA

	Raw Score	Standard Score	T score
Trials Administered	WCST:RAW1		
Total Correct	WCST:RAW2		
Total Errors	WCST:RAW3	WCST:STAND3	WCST:TSCR3
% Errors	WCST:RAW4	WCST:STAND4	WCST:TSCR4
Perseverative Responses	WCST:RAW5	WCST:STAND5	WCST:TSCR5
% Perseverative Responses	WCST:RAW6	WCST:STAND6	WCST:TSCR6
Perseverative Errors	WCST:RAW7	WCST:STAND7	WCST:TSCR7
% Perseverative Errors	WCST:RAW8	WCST:STAND8	WCST:TSCR8
Nonperseverative Errors	WCST:RAW9	WCST:STAND9	WCST:TSCR9
% Nonperseverative Errors	WCST:RAW10	WCST:STAND10	WCST:TSCR10
Conceptual Level Responses	WCST:RAW11		
% Conceptual Level Responses	WCST:RAW12	WCST:STAND12	WCST:TSCR12

	Raw Score
Categories Completed	WCST:RAW13
Trials to Complete 1 stCategory	WCST:RAW14
Failure to Maintain Set	WCST:RAW15
Learning to Learn	WCST:RAW16

(If necessary, enter ≤as <= and ≥as >=)

Comments for page: WCST: COMMENT

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Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Test of Everyday Attention Pilot Transfusion Trial Subject ID: Site: {visit.label}

Date of Assessmen	t: DD MMM	SMO / TEAS: ASSYR YYYY	Version	C (TEAS:VERSION) A	□ (TEAS:VERSION) B	C (TEAS:VERSION)	(The version administered at study completion must be different from the version used at study entry.)
Subtest 1: N	Map Search			Scaled-scores			
Symbo	ols circled in one minute	reas:st1Q1		MS1 TEAS:MS1			
Symbo	ols circled in two minutes	TEAS:ST1Q2		MS2 TEAS:MS2			
	Elevator Counting rrectly-counted strings	AS:ST2Q1	□ (TEA	S:ST2NORM)7 = norm S:ST2NORM)6 = poss al S:ST2NORM) ≤5 = ab	ibly		
Subtest 3: E	Elevator Counting with Di	straction		Scaled-scores			
Cor	rrectly-counted strings TEF (Rule out hearing impairm	as:sT3Q1 ents)		ECD TEAS: ECD			
Subtest 4: \	/isual Elevator						
	Total time taken for correct items (seconds) TEAS:ST4TIME ÷	Total number of switches for the correct items TEAS: ST4SWIT		TEAS:ST4SCOR Timing s (seconds per switch)	core		
				Scaled-scores			
	Raw accuracy score	TEAS:ST4Q1		VE1 TEAS:VE1			
	Timing score	TEAS:ST4Q2		VE2 TEAS: VE2			
Subtest 5: E	Elevator Counting with Re			Scaled-scores			
	Correctly-counted strings	TEAS:ST5Q1		ECR TEAS: ECR			
Subtest 6: T	Telephone search	Total num	nber of				
	Time taken (seconds) TEAS:ST6TIME	correctly- symbols (ign false pos	nore any itives)		• A Raw score (time per	r target score)	
		Scaled-scores					
Time per tar	get score TEAS:ST6Q1	TS TEAS: TS					

Subtest 7: Telephone Search While Counting

Total number of Time taken (seconds)

correctly-circled symbols (ignore any false positives)

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TEAS:ST7TIME ÷	TEAS:ST7CORR	TEAS:ST7B BTime per	target score	
Number of strings of tones correctly counted TEAS:ST7STR :	Number of strings of tones attempted TEAS:ST7C C =	TEAS: ST7D D Proportion	on correctly counted	
Re-enter B here TEAS: ST7REB	Re-enter Dhere TEAS:ST7RED		per target weighted for acc	curacy
Re-enter Ehere TEAS:ST7REE —	Re-enter Ahere TEAS:ST7REA	TEAS:ST7DUAL Dual ta	isk decrement	
Dual task decrement	Scaled-s TEAS:ST7Q1 TSC TEA			
Subtest 8: Lottery	Scaled-s	scores		
Number of responses with at least one letter correct and in the correct position	TEAS:ST8Q1 L TEA	S:L		
Comments for page: TEAS: COMMENT				
Submit Ouery Cancel	Form Co	empletion Help	Print	x Rho
		r r		

Version: 17 Jun 2009 43

Neuropsychological
Dysfunction and
Neuroimaging Abnormalities
in Neurologically Intact Adult
Patients With Sickle Cell
Disease

CVLT-II

Pilot Transfusion Trial

Date of Assessment:

CVL2:ASSDA / CVL2:ASSMO / CVL2:ASSYR

D

MMM

YYYY

{visit.label}

Subject ID: Site:

Level of Recall

Level of Immediate Recall	Number	Correct	Level of Delayed Recall	Number	· Correct
	Raw	Standard Score		Raw	Standard Score
Trial 1	CVL2:CORRAW1	CVL2:CORSTN1	Short Delay Free Recall	CVL2:CORRAW6	CVL2:CORSTN6
Trial 4	CVL2:CORRAW4	CVL2:CORSTN4	Long Delay Free Recall	CVL2:CORRAW7	CVL2:CORSTN7
Trials 1-4 Total	CVL2:CORRAW5	CVL2:CORSTN5	Long Delay Cued Recall	CVL2:CORRAW8	CVL2:CORSTN8
		(T-Score)			

Learning Characteristics, Trials 1-4 Total

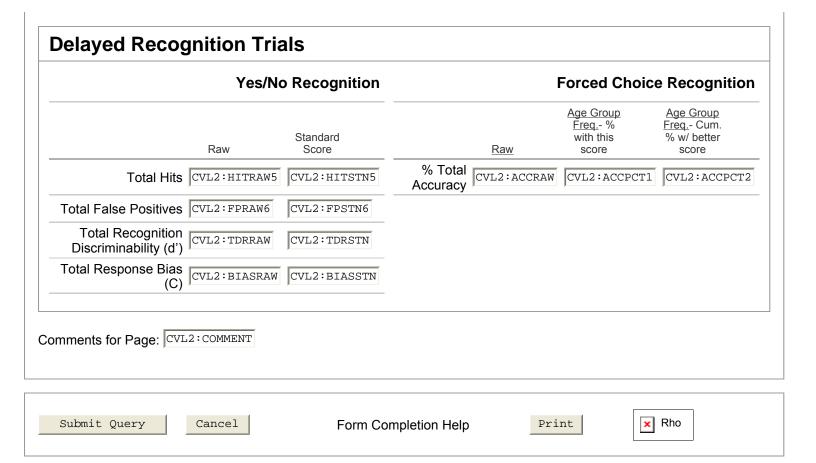
	Raw	Standard Score
Semantic Clustering (Chance Adjusted)	CVL2:SEMRAW	CVL2:SEMSTN
Serial Clustering Bidirectional (Chance Adjusted)	CVL2:SERRAW	CVL2:SERSTN
Subjective Clustering Bidirectional (Chance Adjusted)	CVL2:SUBRAW	CVL2:SUBSTN
Total Learning Slope Trials 1-4	CVL2:TLSTRAW	CVL2:TLSTSTN

Recall Contrast Measures

	Percent Change	Z-Score Difference
Short-Delay Retention (Short Delay Free Recall vs. Trial 4)	CVL2:SDRPCT	CVL2:SDRZSCR
Long-Delay Retention (Long Delay Free Recall vs. Short Delay Free Recall)	CVL2:LDRPCT	CVL2:LDRZSCR

Recall Errors

	Raw	Standard Score
Total Repetitions (All Recall Trials)	VL2:REPRAW4	CVL2:REPSTN4
Total Intrusions (All Recall Trials, All Types)	VL2:INTRAW3	CVL2:INTSTN3
Total Recall Discriminability (List A, All Trials vs. Total Intrusions)	VL2:DISCRAW	CVL2:DISCSTN



Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

WMS-III

Pilot Transfusion Trial

{visit.label}

Subject ID:

Site:

Date of Assessment:

WMS3:ASSDA / WMS3:ASSMO / WMS3:ASSYR

DD

MMM

YYYY

Primary Subtest Total Scores	Raw Scores	Auditory Immediate	Visual Immediate	Immediate Memory	Auditory Delayed	Visual Delayed	Auditory Recognition Delayed	General Memory	Reference Group Scaled Scores
Logical Memory I Recall Total Score	WMS3:LOG1RAW	WMS3:LOG1AIM		WMS3:LOG1MEM		•	•		WMS3:LOG1SCL
Faces I Recognition Total Score	WMS3:FAC1RAW		WMS3:FAC1VIM	WMS3:FAC1MEM					WMS3:FAC1SCL
Verbal Paired Associates I Recall Total Score	WMS3:VER1RAW	WMS3:VER1AIM		WMS3:VER1MEM					WMS3:VER1SCL
Family Pictures I Recall Total Score	WMS3:FAM1RAW		WMS3:FAM1VIM	WMS3:FAM1MEM					WMS3:FAM1SCL
Logical Memory II Recall Total Score	WMS3:LOG2RAW				WMS3:LOG2AD			WMS3:LOG2GM	WMS3:LOG2SCL
Faces II Recognition Total Score	WMS3:FAC2RAW					WMS3:FAC2VD		WMS3:FAC2GM	WMS3:FAC2SCL
Verbal Paired Associates II Recall Total Score	WMS3:VER2RAW				WMS3:VER2AD			WMS3:VER2GM	WMS3:VER2SCL
Family Pictures II Recall Total Score	WMS3:FAM2RAW					WMS3:FAM2VD		WMS3:FAM2GM	WMS3:FAM2SCL
Auditory Recognition Delayed Total Score	WMS3:AUDRAW						WMS3:AUDARD	WMS3:AUDGM	WMS3:AUDSCL
Sums of Scaled Scores		WMS3:SUMAIM	WMS3:SUMVIM	WMS3:SUMMEM	WMS3:SUMAD	WMS3:SUMVD	WMS3:SUMARD	WMS3:SUMGM	

Auditory Recognition Delayed Total Score Calculation

LM II Recognition Total Score	VPA II Recognition Total Score	Auditory Recognition Delayed Total Score
WMS3:ARDLM2	₩MS3:ARDVPA2	■ WMS3:ARDARDT
(Range= 0 - 30)	(Range= 0 - 24)	(Range= 0 - 54)

I	1	1		\downarrow	I	1
\	\	\	\	\	\	\

Index Scores	Auditory Immediate	Visual Immediate	Immediate Memory	Auditory Delayed	Visual Delayed	Auditory Recognition Delayed	General Memory
Sum of Scaled Scores	WMS3:AISUM	WMS3:VISUM	WMS3:IMSUM	WMS3:ADSUM	WMS3:VDSUM	WMS3:ARDSUM	WMS3:GMSUM
Index Scores	WMS3:AIINDEX	WMS3:VIINDEX	WMS3:IMINDEX	WMS3:ADINDEX	WMS3:VDINDEX	WMS3:ARDINDX	WMS3:GMINDEX
Percentiles	WMS3:AIPCT	WMS3:VIPCT	WMS3:IMPCT	WMS3:ADPCT	WMS3:VDPCT	WMS3:ARDPCT	WMS3:GMPCT
Confidence Intervals	WMS3:AICONF	WMS3:VICONF	WMS3:IMCONF	WMS3:ADCONF	WMS3:VDCONF	WMS3:ARDCONF	WMS3:GMCONF

Enter all confidence

Version: 18 Feb 2009

intervals as a range, X-Y	WMS3:INTERVL						
Comments for p	page: WMS3:COM	MENT					
Submit Q	uery Can	ncel	Form Com	pletion Help	Print	×	Rho

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

SF-36

Pilot Transfusion Trial

{visit.label}

Subject ID:

Site:

Initial or End of Phase II?	Date Form	SF36:FORMDA	/ SF36:FORMMO /	SF36:FORMYR	
SF36:INITEND) Initial	Completed:				
\square (SF36:INITEND) End of Phase I	I	DD	MMM	YYYY	
F-36v2 TM Health Survey					
his survey asks for your views about you	r health. This information	will help you keep	track of how you feel and	d how well you are able to do	your usual activities
nswer every question by selecting the ar	nswer as indicated. If you	are unsure about h	ow to answer a questior	n, please give the best answe	r you can.
n general, would you say your health is:	[Click on the box that best	t describes your an	swer.]		
(SF36:SFQ1) Excellent					
(SF36:SFQ1) Very Good					
(SF36:SFQ1) Good					
(SF36:SFQ1) Fair					
(SF36:SFQ1) Poor					
Compared to one year ago, how would yo	ou rate your health in gene	eral now?			
(SF36:SFQ2) Much better now th	an one year ago				
(SF36:SFQ2) Somewhat better no	w than one year ago				
(SF36:SFQ2) About the same as	one year ago				
(SF36:SFQ2) Somewhat worse now	than one year ago				
(SF36:SFQ2) Somewhat worse now (SF36:SFQ2) Much worse now tha	than one year ago n one year ago ut activities you might	do during a typ	pical day. Does you	<i>ır health now limit</i> you ir	n these activities
(SF36:SFQ2) Somewhat worse now (SF36:SFQ2) Much worse now tha	than one year ago n one year ago ut activities you might	do during a tyγ	oical day. Does you Yes, limited a lot	Yes,	No, not
(SF36:SFQ2) Somewhat worse now (SF36:SFQ2) Much worse now that he following questions are about	than one year ago n one year ago It activities you might on each line.]		Yes, limited a lot	Yes, limited a little	No, not limited at a
(SF36:SFQ2) Somewhat worse now that (SF36:SFQ2) Much worse now that The following questions are about so, how much? [Select an option]	than one year ago n one year ago it activities you might on each line.]	ipating in strenuou	Yes, limited a lot S (SF36:SFQ3A	Yes, limited a little (SF36:SFQ3A)	No, not limited at a:
(SF36:SFQ2) Somewhat worse now that (SF36:SFQ2) Much worse now that The following questions are about so, how much? [Select an option] 1. Vigorous Activities, such as running, list sports 1. Moderate Activities, such as moving a playing golf	than one year ago n one year ago it activities you might on each line.]	ipating in strenuou	Yes, limited a lot	Yes, limited a little (SF36:SFQ3A) (SF36:SFQ3B)	No, not limited at a:
(SF36:SFQ2) Somewhat worse now that (SF36:SFQ2) Much worse now that The following questions are about so, how much? [Select an option Vigorous Activities, such as running, list sports and Moderate Activities, such as moving a playing golf. Lifting or carrying groceries	than one year ago n one year ago it activities you might on each line.]	ipating in strenuou	Yes, limited a lot S	Yes, limited a little (SF36:SFQ3A) (SF36:SFQ3B) (SF36:SFQ3C)	No, not limited at a (SF36:SFQ3/
(SF36:SFQ2) Somewhat worse now that (SF36:SFQ2) Much worse now that The following questions are about o, how much? [Select an option Vigorous Activities, such as running, listoris Moderate Activities, such as moving a playing golf Lifting or carrying groceries Climbing several flights of stairs	than one year ago n one year ago it activities you might on each line.]	ipating in strenuou	Yes, limited a lot S	Yes, limited a little (SF36:SFQ3A) (SF36:SFQ3B) (SF36:SFQ3C) (SF36:SFQ3D)	No, not limited at a (SF36:SFQ3) (SF36:SFQ3) (SF36:SFQ3)
(SF36:SFQ2) Somewhat worse now that (SF36:SFQ2) Much worse now that The following questions are about to, how much? [Select an option of the following questions are about to, how much? [Select an option of the following select an option of the	than one year ago n one year ago it activities you might on each line.]	ipating in strenuou	Yes, limited a lot S (SF36:SFQ3A O (SF36:SFQ3B (SF36:SFQ3C	Yes, limited a little (SF36:SFQ3A) (SF36:SFQ3B) (SF36:SFQ3C) (SF36:SFQ3D) (SF36:SFQ3E)	No, not limited at a: (SF36:SFQ3) (SF36:SFQ3) (SF36:SFQ3) (SF36:SFQ3)
(SF36:SFQ2) Somewhat worse now (SF36:SFQ2) Much worse now that The following questions are about so, how much? [Select an option Wigorous Activities, such as running, list sports Moderate Activities, such as moving a playing golf Lifting or carrying groceries Climbing several flights of stairs Climbing one flight of stairs Bending, kneeling, or stooping	than one year ago n one year ago it activities you might on each line.]	ipating in strenuou	Yes, limited a lot (SF36:SFQ3A (SF36:SFQ3B (SF36:SFQ3C	Yes, limited a little (SF36:SFQ3A) (SF36:SFQ3B) (SF36:SFQ3C) (SF36:SFQ3D) (SF36:SFQ3E) (SF36:SFQ3F)	No, not limited at a: (SF36:SFQ36 (SF36:SFQ36 (SF36:SFQ36 (SF36:SFQ36 (SF36:SFQ36 (SF36:SFQ36
(SF36:SFQ2) Somewhat worse now that (SF36:SFQ2) Much worse now that The following questions are about so, how much? [Select an option] 1. Vigorous Activities, such as running, list sports 1. Moderate Activities, such as moving a playing golf 1. Lifting or carrying groceries 1. Climbing several flights of stairs 1. Climbing one flight of stairs 1. Bending, kneeling, or stooping 1. Walking more than a mile	than one year ago n one year ago it activities you might on each line.]	ipating in strenuou	Yes, limited a lot S	Yes, limited a little (SF36:SFQ3A) (SF36:SFQ3B) (SF36:SFQ3C) (SF36:SFQ3D) (SF36:SFQ3B) (SF36:SFQ3B) (SF36:SFQ3F) (SF36:SFQ3F)	No, not limited at a: [SF36:SFQ3] [(SF36:SFQ3] [(SF36:SFQ3] [(SF36:SFQ3] [(SF36:SFQ3] [(SF36:SFQ3] [(SF36:SFQ3]
(SF36:SFQ2) Somewhat worse now (SF36:SFQ2) Much worse now that The following questions are about so, how much? [Select an option A. Vigorous Activities, such as running, list sports D. Moderate Activities, such as moving a playing golf E. Lifting or carrying groceries H. Climbing several flights of stairs E. Climbing one flight of stairs Bending, kneeling, or stooping Walking more than a mile	than one year ago n one year ago it activities you might on each line.]	ipating in strenuou	Yes, limited a lot S	Yes, limited a little (SF36:SFQ3A) (SF36:SFQ3B) (SF36:SFQ3C) (SF36:SFQ3D) (SF36:SFQ3E) (SF36:SFQ3F) (SF36:SFQ3F) (SF36:SFQ3F) (SF36:SFQ3H)	No, not limited at a:

^{4.} During the *past 4 weeks*, how much of the time have you had any of the following problems with your work or other regular daily Version: 18 Feb 2009

;	activities as a result of your physical health?					
		All of the tim		Some of the time	A little of the time	None of the time
i	 a. Cut down on the amount of time you spent on work of other activities 	(SF36:SF	Q4A)) [SF36:SFQ4A)	(SF36:SFQ4A)	(SF36:SFQ4A)
I	b. Accomplished less than you would like	(SF36:SF	Q4B)) [SF36:SFQ4B)	(SF36:SFQ4B)	(SF36:SFQ4B)
(c. Were limited in the <i>kind</i> of work or other activities	(SF36:SF	Q4C) SF36:SFQ4C	(SF36:SFQ4C)	(SF36:SFQ4C)	(SF36:SFQ4C)
(d. Had <i>difficulty</i> performing the work or other activities (example, it took extra effort)	for (SF36:SF	Q4D) (SF36:SFQ4D) [SF36:SFQ4D]	(SF36:SFQ4D)	(SF36:SFQ4D)
	During the past 4 weeks, how much of the tir activities as a result of any emotional problem				our work or othe	r regular daily
		All of the time	Most of the time	Some of the time	A little of the time	None of the time
á	a. Cut down on the <i>amount of time</i> you spent on work or other activities	(SF36:SFQ5A)	(SF36:SFQ5A)	(SF36:SFQ5A)	(SF36:SFQ5A)	(SF36:SFQ5A)
İ	b. Accomplished less than you would like	(SF36:SFQ5B)	(SF36:SFQ5B)	(SF36:SFQ5B)	(SF36:SFQ5B)	(SF36:SFQ5B)
(c. Did work or activities less carefully than usual	(SF36:SFQ5C)	(SF36:SFQ5C)	(SF36:SFQ5C)	(SF36:SFQ5C)	(SF36:SFQ5C)
	During the past 4 weeks, to what extent has your physic or groups? (SF36:SFQ6) Not at all (SF36:SFQ6) Slightly (SF36:SFQ6) Moderately	al health or emotions	al problems interfered wi	th your normal social	activities with family,	friends, neighbors,
	☐ (SF36:SFQ6) Quite a bit					
	(SF36:SFQ6) Extremely					
	How much bodily pain have you had during the past 4 w (SF36:SFQ7) None (SF36:SFQ7) Very Mild (SF36:SFQ7) Mild (SF36:SFQ7) Moderate (SF36:SFQ7) Severe (SF36:SFQ7) Very Severe 8. During the past 4 weeks, how much did pain interference of the past 4 weeks, how much did pain		work (including both wor	k outside the home ar	nd housework)?	
	☐ (SF36:SFQ8) Quite a bit ☐ (SF36:SFQ8) Extremely					
(These questions are about how you feel and give the one answer that comes closest to the	e way you have	e been with you <i>dur</i> been feeling.	ing the past 4 we	eks. For each qu	estion, please
	How much of the time during the past 4 week	All of	Most of	Some of	A little of	None of
i	a. Did you feel full of life?	the time (SF36:SFQ9A)	the time (SF36:SFQ9A)	the time (SF36:SFQ9A)	the time (SF36:SFQ9A)	the time (SF36:SFQ9A)
		(SF36:SFQ9A)		(SF36:SFQ9A)	(SF36:SFQ9A)	(SF36:SFQ9A)
	Have you felt so down in the dumps that nothing	(SF36:SFQ9C)	_	(SF36:SFQ9C)	(SF36:SFQ9C)	(SF36:SFQ9C)
-		(SF36:SFQ9D)	(SF36:SFQ9D)	(SF36:SFQ9D)	(SF36:SFQ9D)	(SF36:SFQ9D)

е	. Did you have a lot of energy?	(SF36:SFQ9E)	(SF36:SFQ9E)	(SF36:SFQ	9E) [SF36:SF	FQ9E)
f.	Have you felt downhearted and depressed	(SF36:SFQ9F)	(SF36:SFQ9F)	(SF36:SFQ	9F) [(SF36:SF	FQ9F)
g	. Did you feel worn out?	(SF36:SFQ9G)	(SF36:SFQ9G)	(SF36:SFQ9	9G) [(SF36:SF	FQ9G) (SF36:SFQ9G)
h	. Have you been happy?	(SF36:SFQ9H)	(SF36:SFQ9H)	(SF36:SFQ	ЭH) П (SF36:SF	FQ9H)
i.	Did you feel tired?	(SF36:SFQ9I)	(SF36:SFQ9I)	(SF36:SFQ	9I)	FQ9I)
	During the <i>past 4 weeks</i> , how much of the time has yetc.)?	our physical health o	r emotional problems	s interfered with yo	ur social activities (l	ike visiting friends, relatives,
	(SF36:SFQ10) All of the time					
	\square (SF36:SFQ10) Most of the time					
	\square (SF36:SFQ10) Some of the time					
	SF36:SFQ10) A little of the time					
	(SF36:SFQ10) None of the time					
			•			
11.	How TRUE or FALSE is <i>each</i> of the follow	•	•	Don't know	Mostly false	Definitely false
		ring statements for Definitely true (SF36:SFQ11A)	•	Don't know	_	Definitely false
		Definitely true	Mostly true	(SF36:SFQ11A)	(SF36:SFQ11A)	_
	a. I seem to get sick a little easier than other people	Definitely true (SF36:SFQ11A)	Mostly true (SF36:SFQ11A)	(SF36:SFQ11A)	(SF36:SFQ11A)	(SF36:SFQ11A)
	a. I seem to get sick a little easier than other people b. I am as healthy as anybody I know	Definitely true (SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)	Mostly true (SF36:SFQ11A) (SF36:SFQ11B)	(SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)	(SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)	(SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)
	a. I seem to get sick a little easier than other people b. I am as healthy as anybody I know c. I expect my health to get worse	Definitely true (SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)	Mostly true (SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)	(SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)	(SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)	(SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)
	a. I seem to get sick a little easier than other people b. I am as healthy as anybody I know c. I expect my health to get worse d. My health is excellent	Definitely true (SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)	Mostly true (SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)	(SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)	(SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)	(SF36:SFQ11A) (SF36:SFQ11B) (SF36:SFQ11C)

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Randomization

Pilot Transfusion Trial

{visit.label}

Subject ID:

	Site:
Into which arm is this subject being randomized?	
\square (RAND:ARM) Chronic transfusion regimen for 6 months	
\square (RAND:ARM) Standard care based on disease symptoms	
Date of Randomization: RAND:RANDDA / RAND:RANDMO / RAND:RANDYR	
DD MMM YYYY	
Comments for page: RAND: COMMENT	
Submit Query Cancel Form Completion Help	Print Rho

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Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Transfusion

Pilot Transfusion Trial

Subject ID: Site:

omplete this shaded section for <u>fe</u>	male subjects only:		
Ask all female subjects of child-bearing potential the	following question when the pre-	transfusion blood sample is dr	awn:
Do you suspect that you are pregnant?	(TRAN:PREGNNT) (TRAN:PREGNNT) (TRAN:PREGNNT)	RAN:PREGNNT)	REGNNT) Not sure
Perform a pregnancy test <u>before transfusion</u> if the sui exclude the subject from the study.	bject replies 'Yes' or 'Not sure'. I	f the subject is pregnant, <u>do no</u>	<u>t</u> perform the transfusion and
	Туре:	(TRAN:TYPE)	(TRAN:TYPE) Serum
	Result:	(TRAN:RESULT)	(TRAN:RESULT)
Pregnancy Test: Date of Collection: DD MMMM	TRAN: COLLYR		
nplete this section for <u>all subjects.</u>			
of Transfusion: TRAN:TRANDA / TRAN:TR	,		

Pre-Transfusion Hb (g/dL):

TRAN: HGB

Pre-Transfusion Hct %:

TRAN: HCT

Pre-Transfusion Hemoglobin Electrophoresis

Sample MUST be obtained within 3 days prior to transfusion. After the first transfusion, pre-transfusion Hb should be ≥ 2.0 g/dL above the baseline, without dropping below 9.0 g/dL. If the subject drops below 9.0 g/dL, then increase the quantity of blood transfused or schedule the next transfusion 1-2 weeks earlier in order to maintain. Consult the Principal Investigator if pre-

	transfusion Hb is < 9.0 g/dL on more than one occasion.
A (%)	TRAN: HBA
S (%)	TRAN: HBS
F (%)	TRAN: HBF
A2 (%)	TRAN: HBA2
Other (%)	TRAN: HBOTH Specify: TRAN: HBOTHS
Direct Coombs' test positive? Indirect Coombs' test positive? Red cell antibody screening results:	Consult Dr. Ken Ataga (919-216-5626), the medical monitor for the study, if the Direct Coombs' test results are questionable, such as weakly positive (not > 1+) or antibodies with no specificity. TRAN: SCRNRES
If red cell antibodies describe	ed, list below and indicate new or known:
	TRAN: ANTIB1 (TRAN: ANTIBIN) (TRAN: ANTIBIN) Known
	TRAN: ANTIB2 (TRAN: ANTIB2N) (TRAN: ANTIB2N) Known
	TRAN: ANTIB3 (TRAN: ANTIB3N) (TRAN: ANTIB3N) Known New
	TRAN: ANTIB4 (TRAN: ANTIB4N) (TRAN: ANTIB4N) Known New
	TRAN: ANTIB5 (TRAN: ANTIB5N) (TRAN: ANTIB5N) Known New
Amount transfused:	RAN:PCELLU Units of packed cells
Did the subject receive more RBCs during this transfusion?	
If yes, specify reason:	TRAN: RBCMAXS
Were the units leukodepleted	? (TRAN:LEUKDEP)Yes (TRAN:LEUKDEP)No
Were the units phenotypically	/ matched?
Did the subject experience a	transfusion reaction? (If yes, complete the Transfusion Reaction form)
omments for page: TRAN: COI	MMENT
Submit Query Ca	ncel Form Completion Help Print Rho

Interval History

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Pilot Transfusion Trial

Subje	ct ID:		
Site:			

Type of contact: INTH:TODAYDA / INTH:TODAYMO / INTH:TO	DDAYYR			
(INTH-CONTACT) Phone call Completion Date: One of the contact of the call of				
Record information since the last study visit (or phone call if a contr	ol subject).			
Yes	(INTH:NEWMED)No			
(If yes, record on Concomitant Medication form.)				
Has the subject had a neurological event, including stroke, TIA, loss of consciousness? (INTRINEUROEV) Yes	(INTH:NEUROEV)NO			
(If yes, complete the Neurological Event form.)				
Record all transfusions that have occurred for any reason other than for this study svisit] button to enter an unscheduled transfusion.	since the subject's last ph	one call or visit (intak	e, study transfusion, or	interval visit). Click the [Add
Date of Transfusion: UTRN:TRANSDA / UTRN:TRANSMO / UTRN:TRANSYN DD MMM YYYYY		ransfused: UTRN: PCELLUN U	nits of packed cells	
Reason for transfusion: UTRN:REASON				
Did subject experience a transfusion reaction?	(UTRN:TRANKXN)Yes	(If yes, comple	te the Transfusion Reaction f	form.)
Were the units leukodepleted?	(UTRN:LEUKDEP)Yes (UTR	N:LEUKDEP)		Remove
Were the units phenotypically matched?	(UTRN: PHENMAT) Yes (UTR	N: PHENMAT)		
Add visit	•	·		
Was the subject treated at home for any new pain event?	METX) NO			
If yes, how many pain events were experienced since the last study visit or phone call?	NUM			
Did the subject receive any pain medication other than Tylenol, aspirin, or Motrin for any pain event?	INMED]NO			
Has the subject begun any new therapies?	WTHR) NO			
If yes, describe: INTH:NEWTHRD				
Pocord all hospitalizations that have popured since the subject's last phone call or visit (intake, etc.	ndy transfusion, or interval visit	Do suro to complete the	a appropriate adverse experi	once form for each beenitalization
Record all hospitalizations that have occurred since the subject's last phone call or visit (intake, stu Click the [Add hospitalization] button to enter a hospitalization.	ldy transfusion, or interval visit). Be sure to complete the	e appropriate adverse experi	ence form for each hospitalization.
		Re act primary reason from t	e appropriate adverse experiences on for Admission the list below and record any, for admission in the space p	pertinent comments
Click the [Add hospitalization] button to enter a hospitalization.		Re ect primary reason from t regarding reason	eason for Admission he list below and record any for admission in the space p	pertinent comments
Click the [Add hospitalization] button to enter a hospitalization.	n∕yy) (sel	ect primary reason from to regarding reason (HOSE) + ADREAS	pason for Admission the list below and record any, for admission in the space p	pertinent comments rovided) [(HOSP-ADREAS) ACS
Click the [Add hospitalization] button to enter a hospitalization.	(sel	Rect primary reason from tregarding reason Grant	eason for Admission the list below and record any, for admission in the space p	pertinent comments rovided) [(HOSP-ADREAS) ACS
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Date of Admission (dd/mmm/yy) Date of Discharge (dd/mmm HOSP:ADMISDA / HOSP:ADMISMO / HOSP:ADMISYR Add hospitalization Record all emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred since tappropriate adverse experience form for each emergency room or unscheduled clinic visits that have occurred the emergency room or unscheduled clinic visits that have occurred the emergency room or unscheduled clinic visits that have occurred the emergency room or unscheduled clinic visits that have occurred the emergency room or unscheduled clin	he subject's last phone concide visit. Click the [Add visit]	Rect primary reason from to regarding reason ADDREAS AD	pason for Admission he list below and record any for admission in the space p (MOSE PLADERAS) Infection (MOSE PLADERAS) Other (MOSE PLADERAS) Other (MOSE PLADERAS) Other (MOSE PLADERAS) Other (MOSE PLADERAS) Other (MOSE PLADERAS) OTHER (MOSE PLADERAS	pertinent comments rovided) (MOSP-ADREAS) ACS : MOSP-ADREASO Remove
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Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Neurological Event

Pilot Transfusion Trial

Subject ID:		
Site:		

Complete this	form for ea	ch Neurologi	cal Even	. DO NOT co	mplete a	ın Adv	erse Ex	perience f	orm.	
	YDA / NEVF:	rodaymo / Nevf	:TODAYYR							
of event: DD	N	IMM	YYYY							
Where was the su	bject first seen	for this event?		(NEVF:SEEN) Hospital	(NEVF:SEF	en) ER	(NEVF:SE	EN) Other, specify	NEVF:SEENOTS	
Was this a Serious If "Yes", submit an		erience (SAE)?		(NEVF:SAE) Yes	(NEVF:SAE	No No				
Were signs or sym	nptoms noted a	t a previous visit?		(NEVF:SYMPTOM) Yes	(NEVF:SYM	MPTOM) No				
Which signs or syr	mptoms occurre	ed? (check all that	t apply)							
(NEVF:LOSSCON)	Loss of	consciousness		(NEVF:BEHAV	(E) Ch	ange in 1	behavior			
(NEVF:MENTAL)	Change i	n mental status		(NEVF:SENDIS	S) Ne	w sensor	y disturban	ce. Specify s	ide: NEVF:SENDISS	
(NEVF:SPEECH)	Loss or with spe	difficulty		(NEVF:VISDIF)) Di	fficulty	with visio	n. Specify si	de: NEVF:VISDIFS	
(NEVF:SWALLOW)	Difficul	ty with swallowi	ng	(NEVF:HEADA	(C) He	adache.	Specify dif	fuse or focal	: NEVF: HEADACS	
(NEVF:BALANCE)	Loss of	balance or dizzi	ness	(NEVF:GAIT)	Ch	ange in	gait or coo	rdination		
(NEVF:SEIZURE)	Seizure			(NEVF:PARAL	Y) Pa	ralysis	or weakness	. Specify side:	NEVF: PARALYS	
Please describe this	s event: NEVF:	DESCNEV								
	_			10 (0) 1 11 11						
_	·		uate this eve	ent? (Check all tha		-	-	trs tolaer)		
(NEVF:MRI)		f brain		(NEVF:ARTERIO	0)		Arteriogram			
(NEVF:CT)	CT sc	an of brain		(NEVF:TCD)		-	rcd			
(NEVF:PET)	PET s	can of brain		(NEVF:TESTOT		(Other, spec	ify: NEVF:TE	ESTOTS	
(NEVF:MRA)	MRA o	f brain								
What was the final	I diagnosis?									
(NEVF:DIAGNO)	Cerebral Infarction	(NEVF:DIAGNO)	Intracrani.	al (NEVF:DIAG	GNO) TIA	(NEVF	F:DIAGNO) Se	eizure [(Other, NEVF:DIAGNO) specif	y: NEVF:DIAGOTS
Was a neurologica investigator?	al evaluation pe	rformed by a stud	у	(NEVF:INVEST) Yes	No (NEVF: IN	VEST)				
Did the event resu	ılt in hospitaliza	tion?		(NEVF:HOSPIT) Yes	(NEVF:HO		(If yes, reco	ord on Interval	History form and su	ıbmint an SAE
Was the subject tra	ansfused for th	is event?		(NEVF:TRANS)Yes	(NEVF:TR	ans)No	(If yes, reco	ord on Interval	History form.)	
Is the event related to s	study intervention?									
(NEVF:RELATED)	Definitely not	(NEVF:RELATED)	Probably not	(NEVF:RELATED)	Possibly	(NEVF		Probably related	(NEVF:RELATED)	Definitely related
What was the outo	come of this eve	ent?								
(NEVF:OUTCOME)	Resolved without sequelae	(NEVF:OUTCOME)	Resolved with sequelae	(NEVF:OUTCOME)	Ongoing	(NEVF	OUTCOME)	Present at death, not contributing to death	(NEVF:OUTCOME)	Death due to AE

(If the subject died, complete the Death form.)

55

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		ate that a copy of the hospitalization records or admission and discha- ould send a detailed description of the event.	arge summaries v	were sent to Rho.
Comments for page:	NEVF: COMMENT			
		5 0 1 1 11 1		Dho.
Submit Query	Cancel	Form Completion Help	Print	x Rho

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Submit Query

Cancel

Adverse Experience

Pilot Transfusion Trial

Subject ID:	
Site:	

× Rho

Print

escribe this Adverse Experience (AE):						
EXP:ADEXPER						
las this a Serious Adverse Experience (SAE)? If "Yes", submit an SAE form.)	(AEXP:SAEYN) Yes (AEXP:SAEYN) No					
ate of onset:	AEXP:ONSETDA / AEXP:ONSETMO / AEXP:ONSETYR					
	DD MMM YYYY					
ate of resolution:	AEXP:RESOLDA / AEXP:RESOLMO / AEXP:RESOLYR					
	DD MMM YYYY					
hat was the outcome?						
nat was the outcome:	☐ (AEXP:OUTCOME) Resolved without sequelae ☐ (AEXP:OUTCOME) Resolved with sequelae					
	(AEXP:OUTCOME) Resolved with sequelae					
	(AEXP:OUTCOME) Ongoing (AEXP:OUTCOME) Present at death, not contributing to death					
	(AEXP:OUTCOME) Present at death, not contributing to death (AEXP:OUTCOME) Death due to AE (complete the Death CRF pg. 28)					
hat was the level of severity?	(Complete an SAE form if the adverse experience resulted in: inpatient hospitalization or prolonging of existing hospitalization, a persistent or significant disability/incapacity, a congenital anomaly/birth defect, a lifethreatening experience, or death. Refer to protocol section 11 for guidelines regarding reporting of AEs and SAEs.)					
hat was the relationship to intervention?	(AEXP:RELATE) Unrelated					
	(AEXP:RELATE) Probably not/remote					
	(AEXP:RELATE) Possibly related					
	(AEXP:RELATE) Probably related					
	(AEXP:RELATE) Definitely related					
hat action was taken? Check all actions taken)	(AEXP:ACTION1) No action					
oneek all delions takerij	\square (AEXP:ACTION2) Study intervention temporarily interrupted					
	(AEXP:ACTION3) Study intervention discontinued					
	(AEXP:ACTION4) Study intervention adjusted					
	(AEXP:ACTION5) Medical intervention					
	(AEXP:ACTION6) Hospitalization					
mments for page: AEXP:COMMENT						

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Form Completion Help

Death

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Pilot Transfusion Trial

Subject ID:
Subject ID.
Site:

Be sure to notify the sponsor, record the event leading to death on corresponding AE CRF (Transfusion Reaction, Neurological Event, OR Adverse Experience), and submit an SAE report. Date of DETH:DEATHDA / DETH:DEATHMO / DETH:DEATHYR (Send a copy of all hospitalization records to Rho. death: Include another copy in the subject's folder) DD MMM Was an autopsy performed? (If yes, be sure to file report in subject's folder) Yes (DETH:AUTOPSY) (DETH:AUTOPSY) Unknown (DETH:AUTOPSY) What was the primary cause of death? (Choose only ONE) Fungal infection (DETH:PRIMARY) Sepsis (DETH:PRIMARY) Progressive (DETH:PRIMARY) (DETH:PRIMARY) Cardiac arrest malignancy (DETH:PRIMARY) Respiratory failure (DETH:PRIMARY) Renal failure Multi-system organ Hepatic failure (DETH:PRIMARY) (DETH:PRIMARY) failure (DETH:PRIMARY) Pneumonia (DETH:PRIMARY) Other Specify: DETH: PRIMOTS Were there secondary causes of Yes death? (DETH:SECCAUS) (DETH:SECCAUS) If yes, what was the secondary cause(s) of death? (Check all that apply.) Fungal infection Sepsis (DETH:FUNGAL) (DETH:SEPSIS) Cardiac arrest (DETH:PROGMAL) Progressive malignancy (DETH:CARDARR) Renal failure (DETH:RESPF) Respiratory failure (DETH:RENALF) (DETH:ORGANF) Multi-system organ failure (DETH:HEPATF) Hepatic failure (DETH:PNEUMO) (DETH:SECOT) Other

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Specify: DETH: SECOTS

Comments for page: DETH: COMMENT			
Submit Query Cancel	Form Completion Help	Print	× Rho

Neuropsychological Dysfunction and Neuroimaging Pilot Transfusion Trial Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease Subject ID: Site: Check this box **after study completion** if this subject did not take any concomitant medications while enrolled in this study. If the subject took any medications while enrolled in (NOCM:NOCMEDS) this study, click the [Add medication] button to enter the concomitant medication. Be sure to record all medications taken by the subject while enrolled in this study **with the** exception of antibiotics or vitamins. Record start date in the dd/mmm/yy format. Record stop date in the dd/mmm/yy format if applicable, or check "Ongoing". Indicate if the information was taken from the medical record or by interview. Start Date Stop Date Check if Medication Indication Information from: Ongoing (dd/mmm/yyyy) (dd/mmm/yyyy) CMED: MEDICAT CMED: INDICAT CMED:STARTDA / CMED:STARTMO / CMED:STARTYR CMED:STOPDA / CMED:STOPMO / CMED:STOPYR ☐ (CMED:ONGOING) ☐ (CMED:RECORD)Medical record ☐ (CMED:INTERV)Interview Remove Add medication Submit Query Cancel Print × Rho Form Completion Help

Concomitant Medications

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Debriefing

Pilot Transfusion Trial

{visit.label}

Subject ID: Site:

P Battery Debriefing								
Date of Battery Completion:	DEB2:NPBATDA /	DEB2:NPBATMO	/ DEB2:NPBATYR		tery tests ninistered by:	DEB2:1	NPBATBY	
Date of Battery Debriefing:	DEB2:BATDBDA /	DEB2:BATDBMO	/ DEB2:BATDBYR		oriefing ducted by:	DEB2:	BATDBBY	
. Did the neuropsycho	ologist provide a complete	d NP debriefing lette	er template?	(DEB2: Yes	BATDBQ1) (DEB2:BAT	FDBQ1)	
	of the completed NP ubject's research reco		ng letter template	(DEB2:BAT	TDBQ2) (DEE	32:BATDB(Q2) (DEB2:BAT	DBQ2)
B. How was the debr	iefing conducted?		(DEB2:BATDBQ3) In person			(DEB2:E	BATDBQ3) e	
			(DEB2:BATDBQ3) Su	bject refu	used [(DEB2:	BATDBQ3) Not	conducted
If conducted, were to during the debriefin	the battery scores interpre g?	ted to the subject, ex	xplaining strengths and w	eaknesses,	(DEB2:BATD		DEB2:BATDBQ4)	(DEB2:BATDBQ4
Reading Achieveme	oject's 9 summary scores (ent; Math Achievement; Na emory and Learning; Mem	aming Skills; Plannin	g and Organization;	(DEB2) Yes	BATDBQ5) (DEB2:BAT	FDBQ5)	
	ubject's 9 summary s led score points) sind			(DEB2: Yes	BATDBQ6) (DEB2:BAT	rdbQ6)	
. If yes, was this char	nge communicated to the	subject and the treat	ing physician?		(DEB2:BATD		DEB2:BATDBQ7)	(DEB2:BATDBQ7)
. Were written res	sults provided to the	subject?		(DEB2) Yes	BATDBQ8) (DEB2:BAT	TDBQ8)	
	e subject provided with ref al services) or were verba				(DEB2:BATD		DEB2:BATDBQ9)	(DEB2:BATDBQ9) N/A

MRI Debriefing									
Date of MRI:	DEB2:MRIDA / DEB2:MRIN	MO / D	EB2:MRIYR		MRI interpreted by:	DEB2:MRIN	ITBY		
Date of MRI Debriefing:	DD MMM DEB2:MRIDBDA / DEB2:MR DD MM		/ DEB2:MRIDBYR		MRI Debriefing conducted by:	DEB2:MRII	DBBY		
Major infarction noted?			(DEB2:INFARCT) Yes		DEB2:INFARCT) No				
If yes, Site 1 (I									
Watershed lesion?			(DEB2:WLESION) Yes		DEB2:WLESION) No)			
Moderate to severe atro	ophy?		(DEB2:ATROPHY) Yes		DEB2:ATROPHY) N	0			
Other serious findings (i.e., hydrocephalus, tumor):		DEB2:OTHFIND						
Did the radiologist	provide a completed MRI debriefing	form?			(DEB2:MRIDBQ1) Yes	(DEB2:MR	RIDBQ1)		
2. If yes, is a copy research record	/ of the MRI debriefing form រ ៅ?	oresent i	in the subject's		(DEB2:MRIDBQ2) Yes	(DEB2:MRID	BQ2)	(DEB2:MI	RIDBQ2)
3. How was the deb	riefing conducted?		(DEB2:MRIDBQ3) I	n		(DEB2		23)	
			(DEB2:MRIDBQ3) S	ubje	ct refused	(DEB2	:MRIDB0	Q3) Not	conducted
4. If conducted, were	the MRI results interpreted to the so	ubject duri	ing the debriefing?		(DEB2:M Yes			RIDBQ4)	(DEB2:MRIDBQ4) N/A
5. Does the subject w	rant the MRI results sent to his/her p	orimary ca	re physician?		(DEB2:MRIDBQ5) Yes	(DEB2:MR	RIDBQ5)		
Comments for page:	DEB2:COMMENT								
	,								

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Study Completion

Pilot Transfusion Trial

{visit.label}

Subject ID: Site:

Completion date:	IO / SCPT:TODAYYR YYYY		
Was subject in the transfusion arm of the study?	☐(SCPT:TRANARM)Yes ☐(SCPT:TRA	NARM)No	
How many transfusions were done during this pha	ase of the study? (include transfusions done	e as a part of the study	and unscheduled transfusions) SCPT: NUMTRAN
Indicate below the components of the study comp	leted. If a component was not completed, s	specify reason why that	particular component was not completed.
History and Physical Exam	☐ (SCPT:HISTOR)Yes	☐ (SCPT:HISTOR) No	If no, reason: SCPT:HISTORR
MMSE	☐ (SCPT:MMSE)Yes	☐ (SCPT:MMSE)No	If no, reason: SCPT:MMSER
POMS	☐ (SCPT: POMS)Yes	☐ (SCPT:POMS)No	If no, reason: SCPT:POMSR
Initial:			
SF-36	□ (SCPT:SF36I)Yes	□ (SCPT:SF36I) No	If no, reason: SCPT:SF36IR
WAIS-III	□ (SCPT:WAIS3I)Yes	□ (SCPT:WAIS3I) No	If no, reason: SCPT:WAIS3IR
Woodcock-Johnson	□ (SCPT:WJR3I)Yes	□ (SCPT:WJR3I) No	If no, reason: SCPT:WJR3IR
D-KEFS	☐ (SCPT:DCFASI)Yes	☐ (SCPT:DCFASI) No	If no, reason: SCPT:DCFASIR
WCST	□ (SCPT:WCSTI)Yes	□ (SCPT:WCSTI) No	If no, reason: SCPT:WCSTIR
TEA	☐ (SCPT:TEAI)Yes	☐ (SCPT:TEAI)No	If no, reason: SCPT:TEAIR
CVLT-II	□ (SCPT:CVLT3I)Yes	□ (SCPT:CVLT3I) No	If no, reason: SCPT:CVLT3IR
WMS-III	□(SCPT:WMS3I)Yes	□ (SCPT:WMS3I) No	If no, reason: SCPT:WMS3IR
MRI	☐ (SCPT:MRII)Yes	☐ (SCPT:MRII)No	If no, reason: SCPT:MRIIR
End of Study:			
SF-36	☐ (SCPT:SF36E)Yes	□ (SCPT:SF36E) No	If no, reason: SCPT:SF36ER
WAIS-III	☐ (SCPT:WAIS3E)Yes	☐ (SCPT:WAIS3E) No	If no, reason: SCPT:WAIS3ER
Woodcock-Johnson	□ (SCPT:WJR3E)Yes	□ (SCPT:WJR3E) No	If no, reason: SCPT:WJR3ER
D-KEFS	☐ (SCPT:DCFASE)Yes	☐ (SCPT:DCFASE) No	If no, reason: SCPT:DCFASER
WCST	☐ (SCPT:WCSTE)Yes	□ (SCPT:WCSTE) No	If no, reason: SCPT:WCSTER
TEA	☐ (SCPT:TEAE)Yes	☐ (SCPT:TEAE)No	If no, reason: SCPT:TEAER
CVLT-II	□ (SCPT:CVLT3E)Yes	☐ (SCPT:CVLT3E) No	If no, reason: SCPT:CVLT3ER
WMS-III	□ (SCPT:WMS3E)Yes	□ (SCPT:WMS3E) No	If no, reason: SCPT:WMS3ER
MRI	☐ (SCPT:MRIE)Yes	☐ (SCPT:MRIE)No	If no, reason: SCPT:MRIER
MRI Debriefing	□ (SCPT:MRIDEB)Yes	☐ (SCPT:MRIDEB) No	If no, reason: SCPT:MRIDEBR
NP Battery Debriefing	\square (SCPT:NPDEB)Yes	☐ (SCPT:NPDEB) No	If no, reason: SCPT:NPDEBR
□ (SCPT:SUBDISP) Subject completed all comp	onents of the study.		
□ (SCPT:SUBDISP) Subject did not complete th	e study. (If checked, enter the date of last of	contact and select the p	rimary reason for early withdrawal from below.)
Date of last SCPT:LASTCE contact:	DA / SCPT:LASTCMO / SCPT:LASTCYR		
DD	MMM YYYY		

- (COLLINATION)	Adverse experience or significant intercurrent illness Specify: S	CPI.ADVEAPS							
	If AE, did subject die?	□ (SCPT:DEATHYN) Yes			N) [SCPT:DEATHYN)No				
		Date of death:	SCPT: DEATHDA	/ SCPT: DEATHMO	/ SCPT:DEATHYR				
			DD	MMM	YYYY				
	Is the AE related to study intervention?	☐ (SCPT:RELA Yes	TED) □(SCPT	:RELATED)No					
□ (SCPT:WITHDRW	In the doctor's opinion the subject's health, safety and/or well-beir	ng is threatened by	continued partic	ipation in the study					
(SCPT:WITHDRW	Subject was non-adherent, or protocol violation (including more the Specify: SCPT:NONADHS	nan 2 months witho	ut transfusion)						
`		nan 2 months witho	ut transfusion)						
	Specify: SCPT:NONADHS Subject lost to follow-up	nan 2 months witho	ut transfusion)						
☐ (SCPT:WITHDRW)☐ (SCPT:WITHDRW)	Specify: SCPT:NONADHS Subject lost to follow-up	nan 2 months witho	ut transfusion)						
☐ (SCPT:WITHDRW) ☐ (SCPT:WITHDRW) ☐ (SCPT:WITHDRW)	Specify: SCPT:NONADHS Subject lost to follow-up Pregnancy	nan 2 months witho	ut transfusion)						
☐ (SCPT:WITHDRW) ☐ (SCPT:WITHDRW) ☐ (SCPT:WITHDRW) ☐ (SCPT:WITHDRW)	Specify: SCPT:NONADHS Subject lost to follow-up Pregnancy Subject requested to withdraw Specify: SCPT:SUBREQS	nan 2 months witho	ut transfusion)						

Form Completion Help

Submit Query

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Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

WAIS-III Pilot Transfusion Trial {visit.label} Subject ID: Site:

Enter <, >, <	<=, >=, and % a	s necessary.						
				Age-Adjusted Sca	aled Scores			Reference Grou
SUBTESTS	Raw Score	VERBAL	PERF.	VC	РО	WM	PS	Scaled Scores
Picture Completion	WAIS:RAWA		WAIS:PERFA		WAIS: POA			WAIS: SCALEA
ocabulary/	WAIS:RAWB	WAIS: VERBB		WAIS:VCB				WAIS: SCALEB
Digit Symbol- Coding	WAIS:RAWC		WAIS:PERFC				WAIS: PSC	WAIS: SCALEC
Similarities	WAIS:RAWD	WAIS: VERBD		WAIS:VCD				WAIS: SCALED:
Block Design	WAIS:RAWE		WAIS: PERFE		WAIS: POE			WAIS: SCALEE
Arithmetic	WAIS:RAWF	WAIS: VERBF				WAIS:WMF		WAIS: SCALEF
//atrix- Reasoning	WAIS:RAWG		WAIS:PERFG		WAIS: POG			WAIS: SCALEG
Digit Span	WAIS:RAWH	WAIS: VERBH				WAIS:WMH		WAIS: SCALEH
nformation	WAIS:RAWI	WAIS: VERBI		WAIS:VCI				WAIS: SCALEI
Picture Arrangement	WAIS:RAWJ		WAIS: PERFJ					WAIS: SCALEJ
Comprehension	WAIS:RAWK	WAIS: VERBK						WAIS: SCALEK
Symbol Search	WAIS:RAWL		(WAIS:PERFL)				WAIS: PSL	WAIS: SCALEL
etter-Number Sequencing	WAIS:RAWM	(WAIS:VERBM)				WAIS: WMM		WAIS: SCALEM
Object Assembly	WAIS:RAWN		(WAIS:PERFN)					WAIS: SCALEN
Sums of Scaled Scores		WAIS:VERBS	WAIS:PERFS	WAIS:VCS	WAIS: POS	WAIS: WMS	WAIS:PSS	
		VERBAL	PERF.	vc	PO	WM	PS	
		×	×					
Full Scale Sco Perform			WAIS: FULLSS					
	x							
IQ/INDEX SCORES	VIQ	PIQ	FSIQ	VCI	POI	WMI	PSI	
Sums of Scaled Scores	WAIS:VIQSUM	WAIS: PIQSUM	WAIS: FSIQSUM	WAIS: VCISUM	WAIS:POISUM	WAIS:WMISUM	WAIS: PSISUM	
Q/Index Score	WAIS: VIQIND	WAIS:PIQIND	WAIS: FSIQIND	WAIS: VCIIND	WAIS: POIIND	WAIS:WMIIND	WAIS: PSIIND	
Percentiles	WAIS:VIQPCT	WAIS: PIQPCT	WAIS: FSIQPCT	WAIS: VCIPCT	WAIS: POIPCT	WAIS:WMIPCT	WAIS: PSIPCT	_
Confidence Intervals	WAIS: VIQCON	WAIS: PIQCON	WAIS:FSIQCON	WAIS: VCICON	WAIS: POICON	WAIS:WMICON	WAIS: PSICON	Enter - U
WAIS:CONFINT								Enter all confidence intervals as a range X-

SUBTESTS	Scaled Score	Mean Score	Mean	WAIS:LEVEL1 Level	(+)	(-)	Standardization Sample
Vocabulary	WAIS:SCALEA2	WAIS: MEANA	WAIS:MDIFFA	WAIS:STATA	\square (WAIS:STRWEKA)	\square (WAIS:STRWEKA)	WAIS:FRQDIFA
Similarities	WAIS:SCALEB2	WAIS: MEANB	WAIS:MDIFFB	WAIS:STATB	□ (WAIS:STRWEKB)	□ (WAIS:STRWEKB)	WAIS: FRQDIFB
Arithmetic	WAIS:SCALEC2	WAIS: MEANC	WAIS:MDIFFC	WAIS:STATC	□ (WAIS:STRWEKC)	□ (WAIS:STRWEKC)	WAIS:FRQDIFC
Digit Span	WAIS:SCALED2	WAIS: MEAND	WAIS:MDIFFD	WAIS:STATD	☐ (WAIS:STRWEKD)	□ (WAIS:STRWEKD)	WAIS:FRQDIFD
Information	WAIS:SCALEE2	WAIS: MEANE	WAIS:MDIFFE	WAIS:STATE	□ (WAIS:STRWEKE)	□ (WAIS:STRWEKE)	WAIS: FRQDIFE
Comprehension	WAIS:SCALEF2	WAIS: MEANF	WAIS:MDIFFF	WAIS:STATF	□ (WAIS:STRWEKF)	□ (WAIS:STRWEKF)	WAIS:FRQDIFF
Letter-Number Sequencing	WAIS:SCALEG2	WAIS: MEANG	WAIS: MDIFFG	WAIS:STATG	□ (WAIS:STRWEKG)	☐ (WAIS:STRWEKG)	WAIS: FRQDIFG
Picture Completion	WAIS:SCALEH2	WAIS: MEANH	WAIS: MDIFFH	WAIS:STATH	□ (WAIS:STRWEKH)	□ (WAIS:STRWEKH)	WAIS: FRQDIFH
Digit Symbol- Coding	WAIS:SCALE12	WAIS: MEANI	WAIS:MDIFFI	WAIS:STATI	□ (WAIS:STRWEKI)	□ (WAIS:STRWEKI)	WAIS: FRQDIFI
Block Design	WAIS:SCALEJ2	WAIS: MEANJ	WAIS:MDIFFJ	WAIS:STATJ	\square (WAIS:STRWEKJ)	□ (WAIS:STRWEKJ)	WAIS:FRQDIFJ
Matrix Reasoning	WAIS:SCALEK2	WAIS: MEANK	WAIS:MDIFFK	WAIS:STATK	□ (WAIS:STRWEKK)	□ (WAIS:STRWEKK)	WAIS:FRQDIFK
Picture Arrangement	WAIS:SCALEL2	WAIS: MEANL	WAIS:MDIFFL	WAIS:STATL	□ (WAIS:STRWEKL)	(WAIS:STRWEKL)	WAIS:FRQDIFL
Symbol Search	WAIS:SCALEM2	WAIS: MEANM	WAIS:MDIFFM	WAIS:STATM	□ (WAIS:STRWEKM)	□ (WAIS:STRWEKM)	WAIS:FRQDIFM
Object Assembly	WAIS:SCALEN2	WAIS: MEANN	WAIS:MDIFFN	WAIS:STATN	☐ (WAIS:STRWEKN)	☐ (WAIS:STRWEKN)	WAIS:FRQDIFN
comments for page:	WAIS: COMMENT						

Neuropsychological Dysfunction and Neuroimaging Abnormalities in Neurologically Intact Adult Patients With Sickle Cell Disease

Transfusion Reaction

Pilot Transfusion Trial

Subject ID: Site:

ate of trans	fusion: TRXN: TRANDA /	TRXN:TRANMO / TRXN:T	TRANYR				
	DD	MMM YY	YY				
Type of reaction: (Check all that apply)	(TRXN:HEMOIMM)	Hemolytic immediate	For all hemolytic reactions, be sure tha Direct and Indirect Coombs' results, specific antibody screening results, and new antibodies identified are included o				
	\Box (TRXN:HEMODEL)	Delayed hemolytic	c the Transfusion case report form.				
	□ (TRXN:NONHEMO)	Febrile, nonhemolytic (fever, chills)					
	\Box (TRXN:ANAPHYL)	Severe anaphylax:	ris				
		(dyspnea, chest constriction, cyanosis)					
	□ (TRXN:ALLERGY)	Other allergic reactions (redness of skin itching, urticaria)	ı,				
	□ (TRXN:FLUIDO)	Fluid overload					
	□ (TRXN:HYPERT)	Hypertension (increase of ≥30 mm Hg over baseline BP)					
	□ (TRXN:OTHRXN)	Other, specify: TRXN:OTHRXNS					
	XN:ONSETDA / TRXN:ONS	ETMO / TRXN:ONSETYR					
of onset:	DD MMM	YYYY	onset: HH MM (24 hour clock format)				

What action was taken? What was the level of severity? (Check all actions taken) (Complete an SAE Mild ☐ (TRXN:NOACT) No action form if the (TRXN:SEVERE) transfusion reaction resulted in: inpatient Transfusion hospitalization or ☐ (TRXN:SEVERE) Moderate ☐(TRXN:TRANINT) interrupted prolongation of temporarily existing hospitalization, a Transfusion ☐ (TRXN:SEVERE) Severe ☐ (TRXN:TRANDIS) persistent or discontinued significant disability/incapacity, Medical ☐ (TRXN:SEVERE) ☐ (TRXN:MEDINT) a congenital threatening intervention anomaly/birth defect, a lifethreatening adverse Death experience, or Hospitalization death. Refer to (Complete ☐ (TRXN:SEVERE) ☐(TRXN:HOSPIT) (Complete an the Death protocol section 11 SAE form) CRF pg.28) for guidelines regarding reporting of AEs and SAEs). Comments for page: TRXN:COMMENT

Submit Query Cancel Form Completion Help Print Rho