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Silent Cerebral Infarct Multi-Center Clinical Trial

Submission date 24/08/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/10/2004	**Overall study status** Completed	
Last Edited 21/08/2014	**Condition category** Haematological Disorders	

Plain English summary of protocol
Not provided at time of registration

Study website
http://sitstudy.wustl.edu

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
U01NS42804

Study information

Scientific Title

Acronym
SIT Trial

Study objectives
On 12/03/2008 this trial record was updated. The start date and anticipated end date of this trial were also updated from 01/04/2000 and 30/04/2005 to 01/12/2005 and 30/11/2012, respectively.

Added as of 12/03/2008:
Primary hypothesis:
1. Prophylactic blood transfusion therapy in children with silent cerebral infarcts will result in at least 86% reduction in the proportion of patients with clinically evident strokes or new or progressive silent cerebral infarcts.

Secondary hypotheses:
1. Prophylactic blood transfusion therapy will limit the further decline in general intellectual abilities when compared to the observation arm.
2. The overall benefit of blood transfusion therapy for silent cerebral infarctions outweighs the risks associated with this therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Sickle Cell Anemia and Stroke

Interventions
Participants will be randomly assigned to one of two groups - the blood transfusion group or the observation group. The blood transfusion group will receive regular blood transfusion therapy. All participants will receive history and physical exams every three months, cognitive testing and neurological exam annually, a TCD 12-18 months following randomization, and a final MRI of the brain at study exit. Active participation on the study is 3 years.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2005

Completion date
30/11/2012

Eligibility

Key inclusion criteria
Inclusion criteria amended as of 12/03/2008:
Inclusion Criteria for Screening:
1. Patient must have sickle cell anemia (hemoglobin SS or sickle B) as confirmed by the local institution by hemoglobin analysis after six months of age
2. Patient must be 5 through 14 years of age (i.e., must have attained their 5th, but not their 15th birthday when the screening consent is signed)
3. Informed consent with assent in accordance with the institutional policies

Inclusion criteria provided at time of registration:
1. Patients ages 6-12 with sickle cell anemia (Hemoglobin SS or SB)
2. Patient must have a silent cerebral infarct documented by magnetic resonance imaging (MRI) of the brain as read by the neuroradiology panel

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Added as of 12/03/2008: Screen 1880; Randomize at least 204 and up to 250

Key exclusion criteria
Exclusion criteria amended as of 12/03/2008:
Exclusion Criteria for Screening at initial screening evaluation and after informed consent has been signed as well as during the interval up to randomization:
1. Patient with a history of a focal neurologic event lasting more than 24 hours with medical documentation or a history of prior overt stroke
2. Patient with other neurological problems, such as neurofibromatosis, lead poisoning, non-febrile seizure disorder, or tuberous sclerosis
3. Patient with HIV infection
4. Pregnancy or lactating females
5. Patient who received treatment with anti-sickling drugs or hydroxyurea within 3 months or anticipate receiving anti-sickling drugs or hydroxyurea during the course of the study
6. Patients on chronic blood transfusion therapy for other reasons
7. Patient judged not likely to be compliant by his/her hematologist and study coordinator based on previous compliance in clinic appointments and following advice. Specifically, families that have missed at least two appointments without notification within 12 months prior to the trial or parents/guardians of potential patients that have been reported for medical or education neglect are not eligible for this trial
8. Patient unable to receive blood transfusion because of alloimmunization
9. Patients who have or anticipate receiving permanent (or semi-permanent) metallic structures attached to their body. (e.g., braces on teeth, body piercings), which their physicians believe will interfere with the MRI of the head to assess the presence of silent cerebral infarct
10. Patients with any person living in the same household who have been randomly assigned in the SIT Trial

Exclusion criteria provided at time of registration:
1. Patients with a history of overt stroke or focal neurological event lasting more than 24 hours
2. Patients with other neurological problems, such as neurofibromatosis, lead poisoning, or tuberous sclerosis
3. Patients with a transcranial doppler (TCD) study with a time-averaged mean velocity greater than 200 cm/sec verified by the study radiologist

Date of first enrolment
01/12/2005

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
United States of America

Study participating centre
WUSM CB 8519
Saint Louis, MO

United States of America
63108

Sponsor information

Organisation
National Institute of Neurological Disorders and Stroke (NINDS) (USA)

Sponsor details
Neuroscience Center, Room 2212
6001 Executive Blvd
Rockville, MD
United States of America
20892

Sponsor type
Government

Website
http://www.ninds.nih.gov/

ROR
https://ror.org/01s5ya894

Funder(s)

Funder type
Government

Funder Name
National Institute of Neurological Disorders and Stroke (NINDS) (USA) (ref: U01NS42804)

Alternative Name(s)
National Institute of Neurological Disorders & Stroke, NIH/National Institute of Neurological Disorders and Stroke, NIH National Institute of Neurological Disorders and Stroke, Instituto Nacional de Trastornos Neurológicos y Accidentes Cerebrovasculares, The National Institute of Neurological Disorders and Stroke, National Institute of Neurological Disorders and Blindness, National Institute of Neurological and Communicative Disorders and Stroke, NINDS, NINDB, NINCDS

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/08/2014		Yes	No