Finding early Indicators of Neurological Damage in Sickle Cell Disease

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Main objective of the current study is to evaluatie clinical, laboratory and genetic risk factors associated with prograssion of neurological damage. The final objective is to make a prognostic model of these risk factors to predict early...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Haemoglobinopathies
Study type	Observational invasive

Summary

ID

NL-OMON35805

Source
ToetsingOnline

Brief title
FIND

Condition

- Haemoglobinopathies
- Blood and lymphatic system disorders congenital
- Central nervous system vascular disorders

Synonym
sickle cell disease, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: neuropsychological functioning, sickle cell disease, stroke, vaso-occlusion

Outcome measures

Primary outcome

Primary outcome is progression of brain infarcts on MRI.

Secondary outcome

Secondary outcome is diminished neurocognitive functioning.

Study description

Background summary

Sickle cell disease is a heriditary hemoglobinopathy leading to irreversible organ damage throughout the body. Brain infarction occurs at a very young age, either accompanied by neurological deficits (overt infarction), or without (silent infarction). These silent infarcts are a risk factor for overt infarction and are associated with diminished neurocognitive functioning. There are several known risk factors for overt infarction, including clinical, laboratory and genetic factors. However, little is known about the etiology and risk factors for silent infarction. Timely recognition of patients at high risk for early neurological damage is important for prevention and treatment of future patients.

Study objective

Main objective of the current study is to evaluatie clinical, laboratory and genetic risk factors associated with prograssion of neurological damage. The final objective is to make a prognostic model of these risk factors to predict early neurological damage.

Study design

The currenct study is an observational study, in part retrospective and in part prospective. At inclusion and after a follow up of 2 years, cerebral MRI is performed, as well as a neurological examination and neuropsychological examination. Furthermore, several laboratory parameters are evaluated yearly, retrospective data is also used. Genetic testing is performed once.

Study burden and risks

The risks of the investigations needed for this research are negligible and the burden to participate is minimal. Children with sickle cell disease are used to frequent appointments in the outpatient clinic, and it is usual for these children to undergo physical examination and MRI scanning. Therefore, neurological examination and neuropsychological testing can be considered similar as compared to normal life of these children.
Appointments will be planned at the same time of the outpatient clinic appointments when possible; the final burden is limited.
The study will be conducted according to the *Code of conduct relating to expressions of objection by minors participating in medical research* approved by the Board of the Dutch Association of Paediatric Medicine.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

Sickle cell disease
Age 8-16
treated at AMC or Erasmus MC

Exclusion criteria

Overt stroke
Chronic blood transfusion scheme
The presence of metal in the body
Claustrofobia

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-09-2011
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL36138.018.11