Cerebral imaging in adults with sickle cell disease using ultra high field magnetic resonance imaging

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To determine whether pathological changes are visible in brain parenchyma, blood vessels or other intracranial structures on ultra high field MRI in SCD patients in normal anatomical areas on 3.0 Tesla MRI and to determine the nature of these...

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

Summary

ID

NL-OMON36437

Source
ToetsingOnline

Brief title
Cerebral Imaging in adults with SCD

Condition

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

Synonym
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: cerebral blood flow, Cerebral infarction, Sickle Cell Disease, Ultra high field MRI

Outcome measures

Primary outcome

The main endpoint is the presence of (pre-) pathological changes of brain parenchyma, blood vessels or other intracranial structures at 7.0 Tesla MRI. Intracerebral changes include cystic infarction, atrophy, encephalomalacia, leukoencephalopathy or changes of the intracerebral blood vessels.

Secondary outcome

Demographical and clinical patient characteristics including age, HbS phenotype, Hb, HbF, leukocytes during stable clinical state, presence of epilepsy.

Cerebral blood flow asymmetry, defined as previously described by Van den Tweel et al.

Neurological examination.

Verbal IQ, performance IQ and full scale IQ, and visuo-motor functioning.

Study description

Background summary

Sickle cell disease is a hereditary hemoglobinopathy which causes chronic hemolysis and vaso-occlusion leading to irreversible damage in multiple organs. Silent braininfarcts (braininfarction without overt neurological deficits) can be seen on conventional MRI in 22-25% of children. These silent infarcts are associated with an increased risk for further infarcts, neuropsychological dysfunction and impairment of cognitive development.

Little is known about the exact etiology and risk factors of silent infarcts, however, early recognition of patients at high risk of silent infarction is of great importance for adequate prevention and treatment. A previous study by the AMC research group on SCD indicated that children with SCD without overt infarctions have left to right asymmetries in cerebral perfusion, this could represent an early stage of pathology in which intervention might prevent further neurologic damage.
Therefore, the purpose of this study is to evaluate the extent and nature of brain parenchymal pathology in patients with SCD without overt infarcts using high field MRI and to investigate a possible association with cerebral blood flow asymmetry and neurocognitive functioning.

Study objective

To determine whether pathological changes are visible in brain parenchyma, blood vessels or other intracranial structures on ultra high field MRI in SCD patients in normal anatomical areas on 3.0 Tesla MRI and to determine the nature of these changes.
To evaluate the association between cerebral blood flow asymmetry and pathological changes of brain parenchyma on ultra high field MRI.
To evaluate the association between neurological examination, neurocognitive functioning and pathological changes of brain parenchyma on ultra high field MRI.
To compare rates of pathological changes visible on 3.0 Tesla and 7.0 Tesla MRI scanning..

Study design

Observational cohort study.

Study burden and risks

The risk of participation in this study is negligible; there are no known side-effects of performing a MRI scan. IIt is usual for patients with sickle cell disease to undergo blood sampling, ultrasonography or MR imaging of the brain. The risks and burden associated with participation in this study are thus comparable to risks and burden of everyday life in patients with sickle cell disease.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients with sickle cell disease
treated at AMC
aged 18-25

Exclusion criteria

Overt stroke, defined as a focal neurological deficit with either motor or sensory deficit lasting more than 24 hr or focal neurological deficit lasting less than 24 hr with neuroimaging evidence of a cerebral infarct corresponding with the focal deficit.
Chronic blood transfusion schedule.
The presence of metal in the body (e.g. osteosynthetic material, pacemaker, artificial cardiac valves).
Claustrophobia.
Surgery performed in the area of measurement in the last 3 months.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-03-2012
Enrollment:	15
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	NL33730.018.10