Cerebral Perfusion Imaging in Children with Sickle Cell Disease

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To sess the relationship between cerebral perfusion and clinical findings (neurological and neuropsychological) in patients with sickle cell disease.To compare iamging fincdings in children with and without sickle cell disease.

Ethical review	Approved WMO
Status	Pending
Health condition type	Red blood cell disorders
Study type	Observational invasive

Summary

ID

NL-OMON33195

Source
ToetsingOnline

Brief title
Cerebral Perfusion in Sickle Cell Disease

Condition

- Red blood cell disorders
- Congenital and hereditary disorders NEC
- Central nervous system vascular disorders

Synonym
Hereditary anemia, Sickle cell disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Arterial Spin Labeling, Cerebral Perfusion, Children, Sickle cell disease

Outcome measures

Primary outcome

Whole brain and regional CBF measured by ASL at 3T MRI (ml/100g/min).

Neurological and neuropsychological findings.

Secondary outcome

Regional arrival time of arterial blood as measured by ASL (ms).

Study description

Background summary

Sickle cell disease is the most common cause of brain infarcts in children. The incidence of sickle cell disease in Europe is increasing; it is the most common hereditary disease in Great-Britain.
Sickle cell disease is en hereditary haemoglobinopathy that causes hemolysis and vaso-occlusion. Vaso-occlsuion leads to irreversible damage in multiple organs e.g. heart, lungs and brain. The cumulative incidence of symptomatic brain infarcts at the age of 9 is 10%. At the age of 18, a silent infarct can be seen on MRI in 35% of children.
It is possible to prevent overt brain infarcts (brain infarcts that cause neurological symptoms) by administration of blood transfusions. Blood transfusion schemes have multiple side effects, like accumulation of iron or allo-immunisation. Therefore, patients who are at a high risk of overt cerebral infarcts are screened by means of trans-cranial ultrasonography.
However, most patients suffer from silent infarcts, with neuropsychological disfunctioning and impairment of cognitive development. Early recognition of patients at high risk of silent infarction is of great importance in adequate prevention or treatment.
A previous study by this group (Stroke 2009) indicated that children with sickle cell disease have asymmetries in cerebral perfusion that cannot be observed in healthy age-matched controls. This could represent an early stage of pathology in which intervention might prevent further neurologic damage.
The purpose of this study is to evaluate if perfusion asymmetries are indeed related to silent infarction and to identify patients at high risk of silent

infarction by using advanced perfusion imaging techniques.

Study objective

To sess the relationship between cerebral perfusion and clinical findings (neurological and neuropsychological) in patients with sickle cell disease.
To compare iamging fincdings in children with and without sickle cell disease.

Study design

Prospective cohort study

Study burden and risks

Group relatedness
This researchquestion is group related. The required knowledge can not be obtained by scanning adult patients.
the pathologic process that causes cerebral damage starts at an early age. The research question thus requires inclusion of subjects in whom this process did not yet cause irreversible damage.
In order to be able to prevent children from silent infarction, early identification of patients who are at risk, is of great importance. Because of the group-relatedness of the research question, an age matched healthy control group is also needed.

Risks are negligible
In the ccmo memorandum of December 2002 "Niet-therapeutisch onderzoek bij wilsonbekwamen: 'nee-tenzij'" a negligible risk is interpreted as a risk that is similar to the risks of everyday life. It is usual for children with sickle cell disease to undergo blood sampling, ultrasonography or MR imaging of the brain. The risks associated with participation in this study are thus comparable to risks of everyday lif in children with sickle cell disease.

Minimal burden
In the ccmo memorandum "Toetsingkader niet-therapeutisch MRI-onderzoek bij minderjarigen of wilsonbekwame proefpersonen" it is stated that MR imaging in children aged eight years and older is acceptable, provided that:
- extensive information is provided to parents and children
- pedagogical support is given
- there is a possibility to practice
- participation is stopped in case of resistance
- research is combined with required diagnostic tests in case of patients

This study will be carried out according to these guidelines. Moreover, the code of behaviour in case of resistance "Verzet in het kader van medisch wetenschappelijk onderzoek (NVK)" will be followed. This means that

participation will be stopped in case of resistance. Parents, doctors and researchers will take care that the child is not feeling uncomfortable or showing any form of resistance.
(Protocol, appendix page 18).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

35 children with sickle cell disease aged between 8 and 20 years, without history of symptomatic infarction and 15 age-matched controls without SCD

Exclusion criteria

The presence of metal in the body (e.g. osteosynthetic material, pacemaker, artificial cardiac valves); claustrophobia; surgery performed in the area of measurement; known or symptomatic brain infarction; already on chronic blood transfusion schedule.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	50
Type:	Anticipated

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	NL28771.018.09