Impaired cerebral autoregulation in patients with sickle cell disease

Published: 30-08-2006
Last updated: 09-05-2024

Aim of the study is to answer the following questions:1. Is cerebral autoregulation impaired in SCD compared to historical control groups and published standard values?2. Do patients with a high level of steady state haemolysis have a more impaired...

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

Summary

ID

NL-OMON29798

Source
ToetsingOnline

Brief title
Cerebral autoregulation in SCD

Condition

- Haemoglobinopathies

Synonym
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: cerbral autoregulation, sickle cell disease

Outcome measures

Primary outcome

Cerebral blood flow velocity, cerebral oxygenation and cerebrovascular CO2 responsiveness (as the percentage increase in MCA Vmean per mmHg increase in PetCO2).

Secondary outcome

Autonomic cardiovascular function (blood pressure, cardiac output and derived parameters)testing using the Ewing*s test battery (a set of short physical exercises: e.g. vassalva maneuver and deep breathing) is used to measure parasympathetic heart rate control, sympathetic cardiovascular control.

Study description

Background summary

The prevalence of stroke among patients with sickle cell disease younger than 19 years of age is 8 %; the lifetime risk is 25 to 30%. Data from literature suggest that young patients with an increased risk on intracerebral infarction may be identified by transcranial Doppler (TCD) analysis of the middle cerebral artery (MCA) flow velocity. Cerebral autoregulation (CA) is defined as the intrinsic capacity to maintain cerebral blood flow more or less constant (CBF) for a range of blood pressures. Therefore an impaired CA might be one of the causes of stroke in sickle cell disease

Study objective

Aim of the study is to answer the following questions:

1. Is cerebral autoregulation impaired in SCD compared to historical control groups and published standard values?

2. Do patients with a high level of steady state haemolysis have a more impaired cerebral autoregulation than patients with a low level of steady state haemolysis?

3. Are there other factors (disease severity, NO-bioavailability, vascular remodeling in other organs and reticulocyte count) associated with impaired cerebral autoregulation and can this be related to its effect on the level of haemolysis?

Study design

In the present study, we analyze the cerebral autoregulation (with cerebral blood flow and cerebral oxygenation as primary endpoints) in 20 sickle cell patients with either a high level of haemolysis (n = 10) or a low grade of haemolysis (n = 10) and this will be compared with healthy (historically) controls. Also the autonomic cardiovascular function and cerebral reserve capacity will be measured.

Study burden and risks

no risks

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

- proven sickle cell disease
- age between 18-35

Exclusion criteria

- HbSC
- History of stroke
- Hypertension (systolic >160 mm Hg or diastolic >100 mm Hg)
- Blood transfusion in the preceding four weeks
- Sickle cell crisis in the preceding two weeks

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	20
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	NL13786.018.06