Circulating endothelial cells in sickle cell disease

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

Summary

ID

NL-OMON30432

Source
ToetsingOnline

Brief title
CEC in SCD

Condition

- Haemoglobinopathies

Synonym
Sickle cell, Sickle cell anemia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Nederlandse Antilliaanse Stichting voor Klinisch Hoger Onderwijs

Intervention

Keyword: Circulating endothelial cells, Sickle cell disease

Outcome measures

Primary outcome

1. Comparison of the number of CEC in sickle cell patients to the number in healthy controls.

Secondary outcome

2. To study the relationship of CEC to the history of clinical vaso-occlusion (e.g., the frequency of painful crises).

3. To analyze the relationship of CEC to established organ damage and dysfunction.

4. To determine the relationship of CEC to laboratory risk factors for poor outcome (e.g., the degree of anemia and the percentage of fetal haemoglobin).

5. To analyze the relationship of CEC to other biomarkers of disease activity (e.g. endothelial activation and fucntion, the hypercoagulable state and angiogenesis.

Study description

Background summary

Sickle cell disease Sickle cell disease (SCD) is the most important hemoglobinopathy worldwide, characterized by chronic hemolysis, increased susceptibility to infections and recurrent vaso-occlusive events that culminate in significant ischemic organ damage resulting in a diminished quality of life and early death. A major problem in the management of SCD is lack of objective tools to accurately assess the extent of the ongoing vaso-occlusive process. An objective laboratory tool to monitor sickle cell vaso-occlusion is paramount as, in most sickle cell patients, the frequency of acute vaso-occlusive events

that require medical care correlates poorly to the ischemic end organ damage characteristic of most sickle cell patients. Ischemic organ damage in SCD develops as a result of ongoing vascular insults initiated by the adhesion of sickle red cells and activated neutrophils to the activated vascular endothelium. Therefore, accurately monitoring ongoing vascular damage could not only help in identifying patients at risk for developing severe organ damage but could also serve as a tool to study the effect of potential therapeutics in clinical trials. Currently, assissing the number of circulating endothelial cells (CEC) in the blood is considered a promising marker of vasculopathy in diseases ranging from atherosclerosis to systemic vasculitis.

Study objective

The objective of this study is to investigate if CEC are elevated in SCD (and if they could therefore serve as a potential tool for assessing SCD activity), and what the relation of CEC is to the patients medical history and to specific laboratory parameters (such as the percentage of fetal hemoglobin and soluble markers of endothelial activation).

Study design

Case-control study

Study burden and risks

The potential risks and burden are minimal, as extra blood (a total of 29 milliliters) will be collected preferably at the moment when blood is being drawn anyway for regular check-ups. Healthy blood donors serve as controls and extra blood will be drawn from them at the moment of blood donation.

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

1. High performance liquid chromatography confirmed diagnosis of HbSS or HbSb0-thalassemia genotype.
2. Written informed consent by the patient.
3. For healthy controls: HbAA genotype, race sex and age matched blood donors, written informed consent.

Exclusion criteria

1. Blood transfusion in the preceding three months.
2. Painful crisis/acute chest syndrome/stroke or other acute complications in the preceding 2 weeks.
3. Pregnancy, active cancer, active infection, connective tissue diseases.
4. For healthy controls: any current disease

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	28-06-2007
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	15-03-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL14742.078.06