Assessment of blood flow velocity and oximetry using non-invasive retinal and cutaneous microcirculation imaging in sickle cell disease (SCD) patients and healthy volunteers.

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Assessment of the cutaneous and retinal microcirculation in SCD patients and matched controls:- Long- and short-term repeatability of LSCI and NiRFI ;- Comparison of cutaneous and retinal microcirculation between SCD patients and matched healthy…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anaemias nonhaemolytic and marrow depression
Study type	Observational invasive

Summary

ID

NL-OMON40787

Source
ToetsingOnline

Brief title
Measurements of bloodflow in sickle cell patients and healthy volunteers.

Condition

- Anaemias nonhaemolytic and marrow depression
- Blood and lymphatic system disorders congenital

Synonym
sickle cell anaemia, Sickle cell disease

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: Biogen,Industry

Intervention

Keyword: Bloodflow, Retina, Sickle cell disease, Validation

Outcome measures

Primary outcome

Retinal blood flow by NiRFI:

- blood flow velocity

- capillary perfusion maps and microvasculature enhancement

- blood oximetry

- metabolic intrinsic state/function

Cutaneous microvascular blood flow by LSCI:

- basal blood flow

- flow upon occlusion-reperfusion

- blood flow upon inspiratory breath holding

Secondary outcome

Not applicable

Study description

Background summary

Peripheral vascular dysfunction has often been observed in Sickle Cell Disease (SCD) patients. The progression of the disease and the risk of complications can be monitored by assessment of the vascular function. However, the

methodology used to assess microvascular function is not uniform, rarely validated and the feasibility unknown. This results in a paucity of data of the appropriate methodology to assess the natural course of microvascular abnormalities and impairs the possibilities to reliably measure possible treatment effects in clinical trials. This project aims to assess the feasibility of three new devices for measurement of the microvasculature in SCD patients, laser speckle contrast imaging and non-invasive retinal function imaging (LSCI and NiRFI).

Study objective

Assessment of the cutaneous and retinal microcirculation in SCD patients and matched controls:
- Long- and short-term repeatability of LSCI and NiRFI ;
- Comparison of cutaneous and retinal microcirculation between SCD patients and matched healthy volunteers;
- The effect of occlusion-reperfusion of the brachial artery and inspiratory breath hold on cutaneous blood flow as assessed by LSCI.

Study design

Open observational single center study in SCD patients and matched healthy volunteers.

- two study days separated by one week
- assessment of cutaneous and retinal microcirculation by LSCI and NiRFI
- two assessments blocks per study day, separated by 1 hour

Study burden and risks

This is an observational study without pharmacological intervention. The main intervention that the study participants will undergo is assessment of vascular function by LSCI and NiRFI, which are all non-invasive methods. In addition, the cutaneous microcirculation will be assessed after occlusion-reperfusion of the brachial artery, and after respiratory manipulation (inspiratory breath holding). These interventions are commonly applied in human studies on vascular functionality, and the risk for the study participants is negligible. Further, study participants will be studied in a state-of the-art clinical unit and medically supervised by qualified medical staff.

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

Inclusion criteria
Sickle cell disease patients
1. Male or female subjects, 18-65 years of age, inclusive;
2. Moderate to severe SCD with a history of at least 4 vaso-occlusive crises in total and at least 1 vaso-occlusive crisis in the last 12 months;;Healthy volunteers
1. Healthy subjects, as defined by the absence of evidence of any active or chronic disease following a medical and surgical history, a physical examination including vital signs.
2. Matched to sickle cell disease patients for gender, age (± 5 years), ethnicity, smoking behavior and body mass index (±3 kg/m2).

Exclusion criteria

Sickle cell disease patients
1. History or symptoms of any significant disease including (but not limited to), neurological, psychiatric, endocrine, cardiovascular, respiratory, gastrointestinal, hepatic, or renal disorder, excluding SCD and conditions that are related to SCD.
2. Recent occurrence (<1 week preceding study day) of a vaso-occlusive crisis, defined as

the need to be admitted to the hospital or to receive supportive treatment.
3. Recent transfusion therapy (<3 weeks preceding study day).
4. Systolic blood pressure (SBP) greater than 140 or less than 90 mm Hg, and diastolic blood pressure (DBP) greater than 90 or less than 50 mm Hg.
5. Concomitant disease or condition that could interfere with the conduct of the study or the study objectives.
(see protocol);Healthy volunteers
1. History or symptoms of any significant disease including (but not limited to), neurological, psychiatric, endocrine, cardiovascular, respiratory, gastrointestinal, hepatic, or renal disorder.
2. Systolic blood pressure (SBP) greater than 140 or less than 90 mm Hg, and diastolic blood pressure (DBP) greater than 90 or less than 50 mm Hg.
3. Concomitant disease or condition that could interfere with the conduct of the study or the study objectives, or that would, in the opinion of the Investigator, pose an unacceptable risk to the study participant.*

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-10-2014
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date:	02-10-2014

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL49940.058.14