Microvascular and red cell rheology assessment in patients with coagulation disorders and hemaglobinopathies

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23084

Source
NTR

Brief title
N.A.

Health condition

INR 2.0-3.0 patients, INR ≥ 3.0 patients, Sickle Cell Disease (SCD) patients, Haemophilia A/B patients, Beta-thalassemia major (TM) patients and healthy volunteers;

Sponsors and support

Primary sponsor: N.A.
Source(s) of monetary or material Support: N.A.

Intervention

Outcome measures

Primary outcome

mDLS measures

1. Directly measured

a. Pulse rate

b. Deep respiratory rate

c. Blood flow

d. Blood flow velocity

e. Traube-Hering waves

2. Indirectly measured

a. Global coagulation status

b. Rheological characteristics of blood

c. Endothelial function

d. Relative cardiac output

e. Vascular health

LSCI measures

1. Basal blood flow

2. Blood flow upon occlusion-reperfusion

Laboratory measures

1. Iron, TIBC and ferritin panel

2. Bilirubin (total and fractionated)

3. Lactate dehydrogenase

4. Prothrombin time (INR) / Activated Partial Thromboplastin Time

5. Fibrinogen

6. Complete blood count with differential

7. Erythrocyte Sedimentation rate (ESR)

8. GDF 11/15

9. Endothelin 1

10. Red cell membrane PS/PE
(Phosphatidylserine/phosphatidylethanolamine)

11. Haptoglobin

12. Hepcidin

Collected data or samples may also be used to derive other measures, when considered to be in line with the objectives of the research protocol.

Secondary outcome

N.A.

Study description

Background summary

Recruitment will take place in the Netherlands

Study objective

This study will be an open observational study with the objective to test the feasibility of the mDLS.

The variability of the methodology over time will be assessed. Blood flow and coagulation status assessed by mDLS and LSCI will be compared with routine laboratory coagulation and red blood cell measures and it will be explored whether mDLS or LSCI-derived coagulation measures discriminate between patients with coagulation disorders, hemoglobinopathies and healthy volunteers.

Study design

Day 1 and Day 16

Intervention

None

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

All subjects must be able to participate and be willing to give written informed consent and to comply with the study restrictions. In addition, eligible subjects must meet the following inclusion criteria:

Healthy volunteers

1. Healthy male or female subjects aged between 18 and 75 years (inclusive);

2. Body mass index between 18-32 kg•m-2 (inclusive).
Patients with target INR of 2.0 – 3.0

1. Male and female subjects aged between 18 and 75 years (inclusive), with stable (for at

least a month) target INR between 2.0 – 3.0;

2. Body mass index between 18-32 kg•m-2 (inclusive).
Patients with target INR ≥3.0

1. Male and female subjects aged between 18 and 75 years (inclusive), with a stable target INR ≥3.0;

2. Body mass index between 18-32 kg•m-2 (inclusive).

Sickle cell disease patients

1. Male and female SCD patients aged between 18 and 75 years (inclusive);

2. Moderate to severe stable SCD (HbSS HbSC or HBS-β thalassemia), with stable disease defined as no significant complications such as VOC, acute chest syndrome or any complication requiring in-patient hospitalization for at least one month prior to the baseline visit, and/or no acute transfusions for at least 2 months prior to the baseline visit.

3. Body mass index between 18-32 kg•m-2 (inclusive).
Haemophilia (hemophilia) patients

1. Haemophilia (hemophilia) patients aged between 18 and 75 years (inclusive);

2. Moderate to severe, stable haemophilia A or B, with a factor activity of -<1%

3. Body mass index between 18-32 kg•m-2 (inclusive).
-thalassemia patients

1. Male and female patients aged between 18 and 75 years (inclusive);

2. Diagnosis of -thalassemia major (TM) as confirmed by hemoglobin electrophoresis and transfusion history.

3. No acute transfusions for at least 1 month (28 days) prior to the baseline or follow-up visits. (Patients may receive a transfusion on day 1 visit after testing is complete and again on day 28 visit after testing is complete)

4. Body mass index between 18-32 kg•m-2 (inclusive).

Exclusion criteria

Eligible subjects must meet none of the following exclusion criteria at baseline:

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;

4. The use of any medication or vitamin/mineral/herbal/dietary supplement within less than 5 half-lives prior to study participation is prohibited, if the Investigator judges that it may interfere with the study objectives;

5. Condition of the skin that prohibits accurate mDLS or LSCI measurements, such as large tattoos, skin ulcers, scar tissue, etc;

6. Unwillingness or inability to comply with the study procedures for any other reason.

Patient populations

1. Any condition that in the opinion of the investigators could potentially jeopardize the health status of the patient;

2. The use of any medication other than required for the patient’s standard treatment, within less than 5 half-lives prior to study participation is prohibited if the Investigator judges that it may interfere with the study objectives;

3. Condition of the skin that prohibits accurate mDLS or LSCI measurements, such as large tattoos, skin ulcers, scar tissue, etc;

4. Unwillingness or inability to comply with the study procedures for any other reason.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2016
Enrollment:	48
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-07-2016
Application type:	First submission

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
NTR-new	NL5762
NTR-old	NTR6004
Other	: CHDR1545

Study results

Summary results

N.A.