Investigating red blood cells of sickle cell patients who started therapy.

No registrations found.

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

Summary

ID

NL-OMON24314

Source
NTR

Brief title
SickleCellScreen

Health condition

sickle cell anemia
HbSS
HbSC
Sikkelcelziekte

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: RR Mechatronics

Intervention

Outcome measures

Primary outcome

Red blood cell deformability

Secondary outcome

Changes in red blood cell deformability over time and correlations with other laboratory parameters and clinical symptoms and signs.

Study description

Background summary

Sickle cell disease (SCD) is a hemoglobinopathy in which a single nucleotide mutation in the beta-globin chain causes the formation of the abnormal hemoglobin S (HbS). When HbS becomes deoxygenated it polymerises, resulting in sickling of red blood cells (RBCs). These sickled RBCs have strongly reduced deformability, leading to vaso-occlusive crises, multi organ failure and chronic hemolytic anemia.

Hydroxyurea is the only approved drug for the treatment of sickle cell disease. It increases the production of fetal hemoglobin (HbF), thereby lowering HbS levels and, consequently, decreases sickling events. There is however no accurate measurement of a dose-and-effect relation, other than the next life-threatening crisis. There also is no all-inclusive surrogate end-point to estimate disease severity.

Altered red blood cell (RBC) deformability is a feature of many RBC disorders, including SCD. It can be measured using the Lorrca (Laser-assisted Optical Rotational Red Cell Analyzer) under varying circumstances. For instance, the hypoxia-hyperoxia ektacytometry module of the Lorrca enables the measurement of RBC deformability in response to changes in oxygen tension. This is particularly relevant in the field of SCD. Variables known to be of influence for sickling (e.g. HbF levels, presence of transfusion blood) can be studied by using one single fully automated, operator independent test. We hypothesize that this single test can determine an individual’s status and/or susceptibility to sickling, and measure the effect of hydroxyurea therapy.

Study objective

Red blood cell deformability improves after start of therapy with Hydroxyurea.

Study design

baseline, after 1, 3 and 6 months.

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

1.„h No blood transfusion within the past 2 months

2. Diagnosed with sickle cell anemia (HbSS, HbSC or HbS/beta-thal)

3. Starting with Hydroxyurea therapy

4. Parents/legal guardians (and child, depending on age) or adult patients must give informed consent

Exclusion criteria

1. Blood transfusion within past 2 months

2. Body weight below 10 kg

3. Age <1 year

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-10-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54704
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6015
NTR-old	NTR6779
CCMO	NL62011.041.17
OMON	NL-OMON54704

Study results