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

Gepubliceerd: 26-10-2017 Laatst bijgewerkt: 19-03-2025

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24314

Bron
Nationaal Trial Register

Verkorte titel
SickleCellScreen

Aandoening

sickle cell anemia
HbSS
HbSC
Sikkelcelziekte

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: RR Mechatronics

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Red blood cell deformability

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

baseline, after 1, 3 and 6 months.

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Blood transfusion within past 2 months

2. Body weight below 10 kg

3. Age <1 year

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2017
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-10-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54704
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten