Discriminating between thalassemias and iron disorders with the Laser optical rotational cell analyser (Lorca).

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Assessing different modalities of ektacytometry in diagnosing thalassemia and/or iron disorders. Investigating the influence of hemoglobinopathies and iron disorders on red cell membrane deformability in comoparison with healthy controls.

Ethical review   Approved WMO
Status   Will not start
Health condition type   Haemoglobinopathies
Study type   Observational invasive

Summary

ID

NL-OMON46020

Source
ToetsingOnline

Brief title
Thalascreen

Condition

- Haemoglobinopathies
- Blood and lymphatic system disorders congenital
- Iron and trace metal metabolism disorders

Synonym
hemoglobinopathy, thalassemia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Intervention

Keyword: ektacytometry, iron, Red blood cell, Thalassemia

Outcome measures

Primary outcome

Investigating ektacytometry in 6 different groups of patients

(alpha-thalassemia trait, alpha-thalassemia homozygote, haemoglobin H disease

and other more rare variants, beta-thalassemia intermedia, iron deficiency

anemia and hereditary hemochromatosis).

Secondary outcome

Correlating ektacytometry data of these patients to clinical data, morphology

of RBCs, haematological parameters and iron status, oxidative stress and

nitrosylation assays, pyruvate kinase activity and stability, methemoglobin and

oxygen saturation.

Study description

Background summary

Ektacytometry is a method which can be used to investigate red blood cell deformability under several different circumstances. Laser Optical Rotational Cell Analyser (Lorca) is a next generation ektacytometer which can be used to measure different aspects of red blood cell (RBC) deformability.
Alpha- and beta-thalassemias are hemoglobinopathies in which a defect in alpha or beta globin chains causes red blood cell changes and eventually haemolytic anemia. Iron deficiency causes microcytosis and hypochromic red blood cells. Iron overload in hemochromatosis causes oxidative stress which results in damage to red blood cells. The damage on red blood cells caused by these different pathologies have different effects on their deformability. This study investigates the deformability of different hemoglobinopathies and iron disorders on red blood cell deformability measured with the Laser optical

rotational cell analyser (Lorca) a next generation ektacyometer.

Study objective

Assessing different modalities of ektacytometry in diagnosing thalassemia and/or iron disorders. Investigating the influence of hemoglobinopathies and iron disorders on red cell membrane deformability in comoparison with healthy controls.

Study design

cross-sectional observational study

Study burden and risks

The study will investigate blood of patients. If possible the venipuncture will be combined with a routine visit. Otherwise one venipuncture is needed.
The subjects will not directly benefit from this study.

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

* > 18 years
* No regular blood transfusions
* Have alpha-thalassemia trait, homozygote alpha thalassemia, Hemoglobin H or other more rare variants where 3 alleles are affected, beta-thalassemia intermedia, iron deficiency anemia or hereditary hemochromatosis
* Be able to give informed consent

Exclusion criteria

* Suffering from another serious condition
* Fever at time of venepuncture
* Inflammatory condition at time of venepuncture
* Not able to give informed consent
* Regular blood transfusions
* Intra venous iron therapy in past 6 months

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	132
Type:	Anticipated

Ethics review

Approved WMO Date:	03-08-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22102
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL56731.041.16
Other	volgt
OMON	NL-OMON22102