

Sickle Cell Disease: Targeting Alloantibody formation Reduction; Risk factors, and Genetics

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In this study, the genetic risk factors and time dependent risk factors for alloimmunization will be analyzed. Furthermore, the role of the innate and adaptive immune system on allo-antibody formation in SCD patients will be elucidated.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Haemoglobinopathies
Study type	Observational invasive

Summary

ID

NL-OMON50758

Source

ToetsingOnline

Brief title

STARRING

Condition

- Haemoglobinopathies
- Blood and lymphatic system disorders congenital

Synonym

Sickle Cell Anemia, Sickle Cell Disease

Research involving

Human

Sponsors and support

Primary sponsor: Sanquin Bloedbank

Source(s) of monetary or material Support: Stichting Sanquin Bloedvoorziening

Intervention

Keyword: Allo-antibody, Alloimmunization, Erythrocyt tranfusion, Sickle Cell Disease

Outcome measures

Primary outcome

The following determinants will be studied:

Time dependent clinical risk factors and genetic risk factors for alloimmunization in SCD patients.

Secondary outcome

Response of the innate and adaptive immune system on a blood transfusion in responders (patients that form allo-antibodies) and non- responders (patients that don*t form allo-antibodies)

Study description

Background summary

The cornerstone in the treatment of sickle cell disease (SCD) patients are blood transfusions. SCD patients receiving blood transfusions are at high risk for alloimmunization, a complicating factor for future blood transfusions, as these patients are at risk for serious complications such as delayed hemolytic transfusion reactions. Moreover, it becomes more challenging to find compatible blood for the patients, as these compatible units are scarce. Extended matching reduces allo-antibody formation; however it is laborious and time-consuming. Presently, only a few genetic and environmental risk factors have been implicated. Inflammatory state at the time of transfusion is associated with allo-antibody formation, which is of importance for SCD patients, as they experience chronic inflammation as a result of chronic hemolysis. However, no prospective studies have been conducted to elucidate allo-antibody formation in the SCD population. Identification of SCD patients at high risk for alloimmunization may help in developing tailored prevention strategies, such as extended matching for patients at high risk for allo-antibody formation.

Study objective

In this study, the genetic risk factors and time dependent risk factors for alloimmunization will be analyzed. Furthermore, the role of the innate and adaptive immune system on allo-antibody formation in SCD patients will be elucidated.

Study design

This is a national, prospective multicenter observational cohort study.

Study burden and risks

Participants in this study will undergo a total of 5 blood sample drawings in 6 months. A total of 180 ml will be drawn from adults and children ≥ 12 years and 110 ml from children < 12 years. The blood sampling will be combined as much as possible with regular outpatient department visits and regular blood control, in order to reduce the burden and additional visits to the hospital. As this is the only intervention, the risk of participating in this study for the patient is negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Sickle Cell disease patient
Need for transfusion
No alloantibodies

Exclusion criteria

>25 transfusions
Chronic transfusion scheme

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 20-09-2017

Enrollment: 150

Type: Actual

Ethics review

Approved WMO

Date: 10-07-2017

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 03-08-2017

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 08-01-2018

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 13-08-2018

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 04-12-2018

Application type: Amendment

Review commission: METC Amsterdam UMC

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	NL60834.018.17