# 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.

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| **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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**Scientific**
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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

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|---|---|
| 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

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|---|---|
| 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 |