

# Determining the role of Von Willebrand factor and ADAMTS13 in the adhesion of sickled erythrocytes to endothelial cells

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To determine the role of VWF and ADAMTS13 in the adherence of sickled erythrocytes to vascular endothelium.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Red blood cell disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON32743

### Source

ToetsingOnline

### Brief title

The role of VWF and ADAMTS13 in vascular occlusion in sickle cell disease

### Condition

- Red blood cell disorders
- Congenital and hereditary disorders NEC

### Synonym

hereditary anemia, sickle cell disease

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** children, sickle cell disease, silent infarcts, von willebrand factor

## Outcome measures

### Primary outcome

Main study parameter is the amount and percentage of adhesion as compared to a baseline measurement with normal erythrocytes.

### Secondary outcome

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## Study description

### Background summary

Vascular occlusion causes devastating complications in patients with sickle cell disease. However, the mechanisms of vascular occlusion are poorly understood. It is hypothesized that disturbances in the ADAMTS13/VWF ratio contribute to the pathophysiology of vascular occlusion in patients with sickle cell disease.

This project aims to elucidate pathophysiology of vascular occlusion in patients with sickle cell disease, focusing on disturbances in the balance between VWF and ADAMTS13.

### Study objective

To determine the role of VWF and ADAMTS13 in the adherence of sickled erythrocytes to vascular endothelium.

### Study design

In vitro study of the interactions between human umbilical vein endothelial cells and sickled erythrocytes under continuous flow.

### Study burden and risks

The first experiments will make use of the waste product of erythrocytapheresis. This causes no increased risks associated with

participation. Since some blood cells may become overly activated after apheresis, later experiments will make use of blood drawn from non-transfused patients. This will entail taken 30 ml of blood extra, next to the normal routine withdrawal. This volume is as small as possible to minimise the possible burden for the patient.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)  
Elderly (65 years and older)

### Inclusion criteria

Adult sickle cell patients with HbSS or HbS\*0 als genotype

## Exclusion criteria

Therapeutic intervention with hydroxyurea (Hydrea), with an extra exclusion criterium for the non-transfused patients that they have not been transfused in the last 4 months.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-10-2009

Enrollment: 10

Type: Anticipated

## Ethics review

Approved WMO

Application type: First submission

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	NL29705.018.09