# SCONE Study Studies on Complement regulation in atypical hemolytic uremic syndrome following hemodialysis, plasmapheresis and treatment with Eculizumab

Published: 09-10-2012 Last updated: 26-04-2024

Objective: To analyze in more detail the complement activation and regulation and especially the functional CFH activity following three types of interventions in patients known with HUS and correlate these to clinical findings. The three...

Ethical review	Approved WMO		
Status	Recruitment stopped		
Health condition type	Renal and urinary tract disorders congenital		
Study type	Observational invasive		

# Summary

### ID

NL-OMON37013

**Source** ToetsingOnline

Brief title SCONE study

### Condition

- Renal and urinary tract disorders congenital
- Immune disorders NEC
- Renal disorders (excl nephropathies)

#### Synonym

hemolytic uremic syndrome, HUS

#### **Research involving**

1 - SCONE Study Studies on Complement regulation in atypical hemolytic uremic syndr ... 20-06-2025

Human

### **Sponsors and support**

Primary sponsor: Universitair Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

#### Intervention

Keyword: Coagulation, Complement, HUS, Intervention

#### **Outcome measures**

#### **Primary outcome**

Tests: -Levels of complement factors: C3, C3b, Complement Factor H quantitative

(ELISA), Complement factor I (ELISA), CFB, sC5-9 membrane attack complex,

Presence of C3b on erythrocytes, Functional assay: Complement Factor H, MCP

expression on leucocytes (flow cytometer), tests of coagulation and endothelial

function, Micro endothelial particles, circulating DNA (nucleosomen), FSAP

(factor VII-activating protease.

#### Secondary outcome

not applicable

# **Study description**

#### **Background summary**

Haemolytic uremic syndrome (HUS) is characterized by haemolysis, thrombocytopenia and renal failure. HUS is caused by dysregulation of the complement system. It accounts for 10% of HUS cases in children and most cases in adults. The complement system is an ancient important component of the innate immune system and protects against invading micro-organism or foreign tissue. However a dysbalance in this system, which can be brought about by multiple factors, results in the clinical syndrome of HUS. Treatment of HUS is plasmaferesis of infusion of a monoclonal antibody directed against the C5-9 complex. Both methods are very expensive. Many uncertainties about optimal dosing and effects of the treatment on the complement system itself remain.

#### **Study objective**

Objective: To analyze in more detail the complement activation and regulation and especially the functional CFH activity following three types of interventions in patients known with HUS and correlate these to clinical findings. The three interventions are hemodialysis, plasmapheresis and infusion of 1200 mg eculizumab (SOLIRIS®).

#### Study design

Study design: Single Center, single cohort, non-randomized trial.

#### Study burden and risks

The burden of this study due to withdrawal of a little amount of blood will be neglect able, the more so since all patients will have an functional access to the bloodcirculation

# Contacts

**Public** Selecteer

Meibergdreef 9 Amsterdam 1105 AZ NL Scientific Selecteer

Meibergdreef 9 Amsterdam 1105 AZ NL

### **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

### **Inclusion criteria**

- age more than 12 years
- diagnosis of atypical HUS
- treatment either with hemodialysis, plasmapheresis or eculizumab
- after giving written informed consent

### **Exclusion criteria**

no informed consent

# Study design

### Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Other	

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2012
Enrollment:	16

4 - SCONE Study Studies on Complement regulation in atypical hemolytic uremic syndr ... 20-06-2025

Type:

#### Actual

# Ethics review

Approved WMO Date: Application type: Review commission:

09-10-2012 First submission 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 CCMO **ID** NL41994.018.12