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

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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

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

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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)
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

Type:	Actual

Ethics review

Approved WMO Date:	09-10-2012
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	NL41994.018.12