Complement activation following acute ischemic stroke

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Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON31843

Source
ToetsingOnline

Brief title
niet van toepassing

Condition

- Central nervous system vascular disorders

Synonym
ischemic stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: afdelingsgeld

Intervention

Keyword: acute ischemic stroke, complement system, inflammation

Outcome measures

Primary outcome

see above

Secondary outcome

see above

Study description

Background summary

Stroke is the third leading cause of death and the first cause of disability in developed countries. The need for effective and widely available therapies is highly evident.
There is growing evidence that inflammation plays an important role in the pathophysiology of ischemic stroke and may contribute to the secondary damage following ischemic stroke. Complement activation may be one of the key pathways in the onset and reinforcement of this inflammation process. Recent animal studies of focal cerebral ischemia showed that the complement system is activated and suggested that complement inhibition may improve stroke outcome.

Study objective

The purpose of the present study is to assess whether the complement system is activated in the acute phase of ischemic stroke by determining the concentration of complement activation products and the remaining function of the three pathways of complement activation in peripheral blood of patients with ischemic stroke.

Study design

Blood samples from 20 patients with ischemic stroke will be collected on admission and on day 1, 2, 3 and 5 and at 1 month. Plasma will be analyzed for components of all three pathways of complement activation by an enzyme-linked immunosorbent assay (ELISA). In addition, plasma will be analyzed for C1q, CH50, C3a, C5a levels by an ELISA. Stroke severity, neurological improvement or worsening will be assessed by means of the NIHSS.

Complement levels drawn from ischemic stroke patients will be compared with complement levels drawn from age and sex matched controls. Regression analysis will be applied to study the association between complement levels and stroke severity and complement levels and neurological outcome.

Study burden and risks

Clinical implications Studying the role of the complement system in the acute phase of ischemic stroke might be very interesting as it may be an important novel therapeutic target.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

a clinical diagnosis of ischemic stroke, the possibility to confirm the diagnosis with CT or MRI within 24 hours after inclusion in the study and admission within 24 hours of symptom onset.

Exclusion criteria

Patients with symptoms of an infection, malignant or other underlying inflammatory disease and/or currently receiving anti-inflammatory or immunosuppressive medication will be excluded.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2008
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-10-2008
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL23838.078.08