Brain specific proteins in tissue macrophages in acute ischemic stroke. Association with functional and radiological outcome; a pilot study.

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To investigate whether the amount of TiMas containing brain specific proteins, correlates with functional outcome and infarct size in patients with acute ischemic stroke. And, to study the kinetics of the tissue macrophages and to compare these data…

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

Summary

ID

NL-OMON40751

Source
ToetsingOnline

Brief title
TiMa in acute ischemic stroke.

Condition

- Central nervous system vascular disorders

Synonym
ischemic stroke, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC

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

Intervention

Keyword: acute ischemic stroke, biomarkers, infarct size, Tissue macrophages

Outcome measures

Primary outcome

Endpoints are curves of biomarker release. The association of TiMA release with

infarct size, neurological outcome and other serum markers will be inspected

with scatterplots, without statistical testing.

Secondary outcome

see above

Study description

Background summary

Stroke is a severely disabling disease. New treatments have been developed and are being evaluated. We need biomarkers of infarct size to rapidly assess treatment effects.

Study objective

To investigate whether the amount of TiMas containing brain specific proteins, correlates with functional outcome and infarct size in patients with acute ischemic stroke. And, to study the kinetics of the tissue macrophages and to compare these data with the kinetics of plasma markers release such as NSE, S100B, CRP, FAPB7 and FABP3, circulating histones and MPO-DNA.

Study design

This is a proof of concept study, formally an observational case series.

Study burden and risks

The burden to individual patients consists of daily bloodsampling from an IV catheter for 5 days, carrying a small risk of cubital hematoma. Additionally,

an non-enhanced MRI will be made to assess infarct size.

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

ischemic stroke onset within 6 hours

Exclusion criteria

use of immunosuppresive medication
pre stroke modified Rankin score > 2

usual contra-indications for MRI

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-06-2015
Enrollment:	9
Type:	Actual

Ethics review

Approved WMO

Date:	10-06-2014
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	NL48968.078.14