Fibrinogen gamma and response to thrombolytic therapy in acute ischemic stroke

Published: 10-06-2010
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The purpose of this project is to determine the impact of pretreatment fibrinogen gamma*/ total fibrinogen ratios on the success of rtPA therapy.

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

Summary

ID

NL-OMON34726

Source
ToetsingOnline

Brief title
Fibrinogen gamma

Condition

- Central nervous system vascular disorders

Synonym
ischemic stroke, stroke

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Fibrinogen gamma, stroke, thrombolysis

Outcome measures

Primary outcome

Neurological improvement by means of the NIHSS at 24 hours and discharge.

Secondary outcome

The extent of fibrinogen breakdown measured by markers of fibrinolysis (such as

plasma D-dimer concentrations).

Study description

Background summary

Intravenous thrombolysis using recombinant tissue plasminogen activator (rtPA) is still the only approved therapy for acute ischemic stroke. Although thrombolytic therapy significantly improves outcome after ischemic stroke, blood supply is not restored in a large proportion of patients, because rtPA infusion does not effectively lyse the clot. A fibrinogen variant, fibrinogen gamma* has prothrombotic properties by increasing the rate of factor XIII activation resulting in denser clot conformation.

Study objective

The purpose of this project is to determine the impact of pretreatment fibrinogen gamma*/ total fibrinogen ratios on the success of rtPA therapy.

Study design

Patients with ischemic stroke, treated with rtPA, will be prospectively studied. All patients will receive computed tomography (CT) scan and computed angiography (CTA) scan at admission and a CT-scan at day 3. Blood samples will be obtained before rtPA treatment and at hours 3, 24 hours and at day 3 after initiation of therapy to determine total fibrinogen, gamma* *fibrinogen and plasma D-concentrations.

Study burden and risks

4 times vena punction for collection of blood.
CT on day 3 (2.1-2.3mSv)

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 acute ischaemic stroke
- a measurable deficit on the NIHSS or NIHSS supplemental motor score
- treatment with intravenous or intra-arterial alteplase

Exclusion criteria

contra-indications for treatment with iv or ia rt-PA, i.e.
-cerebral infarction within the previous 6 weeks,
-a history of intracerebral hemorrhage,
-severe head injury the previous 4 weeks,
-major surgery, gastrointestinal bleeding or urinary tract bleeding within the previous 2 weeks
-arterial blood pressure > 185/110 mmHg,
-blood glucose < 2.7 or > 22.2 mmol/l,
-clinical signs of hemorrhagic diathesis or platelet count <90 x 10*9/L, APTT>50 sec or INR >1.7.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-06-2010
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	NL30811.078.09