DIagnostic AngioGRAphy to find vascular Malformations (DIAGRAM study) in patients with spontaneous intracerebral haemorrhage

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1. To determine the diagnostic accuracy, in terms of detecting a vascular malformation, of CTA, MRI/MRA, DSA, or combinations thereof in patients with ICH?2. To find out which test or combination of tests is most effective for the detection of...

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

Summary

ID

NL-OMON39633

Source
ToetsingOnline

Brief title
Detection of vascular malformations after intracerebral haemorrhage

Condition

- Central nervous system vascular disorders

Synonym
intracerebral haemorrhage, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: angiography, diagnosis, intracerebral haemorrhage, magnetic resonance imaging

Outcome measures

Primary outcome

The primary outcome will be the detection of a vascular malformation with a (combination of) test(s) as expressed by means of the area under the receiver operator characteristic curve.

Using a logistic regression model we will assess which (combination of) test(s) discerns best between presence and absence of a vascular malformation.

Secondary outcome

The secondary outcome will be the effectiveness of the diagnostic tests, separately and in combination, expressed as remaining life expectancy in good health (independent) and the number of quality-adjusted lifeyears (QALY*s).

Study description

Background summary

Rationale:
Background. Spontaneous intracerebral haemorrhage (ICH) accounts for 10-15% of all strokes. ICH may be caused by leakage from small vessels affected by hypertension, by cerebral amyloid angiopathy, in particular in elderly patients, or by bleeding from a vascular malformation. In patients younger than 45 years of age brain arteriovenous malfomation
(AVM) is the most common single cause of ICH. ICH can also be caused by rupture of an aneurysm (without evident subarachnoid haemorrhage), by cavernous angiomas, by venous angiomas, and by dural AVMs. Except for the specific group of patients older that 45 year of age with ICH in the basal ganglia and a history of hypertension, it is unknown which investigations should be done and when in order to find or exclude a vascular malformation in patients with ICH.

Finding a vascular malformation has important prognostic and therapeutic implications.

Study objective

1. To determine the diagnostic accuracy, in terms of detecting a vascular malformation, of CTA, MRI/MRA, DSA, or combinations thereof in patients with ICH?
2. To find out which test or combination of tests is most effective for the detection of vascular malformations with effectiveness expressed as remaining life expectancy in good health and expected numbers of quality-adjusted life-years.

Study design

The study design will be a prospective cohort study of 300 patients with spontaneous ICH. CTA will be performed in the acute phase, preferably immediately after the CT-scan that showed the ICH, but at the latest 48 hours after the ICH occurred. MRI/MRA is performed four or eight weeks after the ICH occurred depending on the size of the ICH. If CTA and MRI/MRA have not shown the cause of the ICH, a DSA will be performed within one week after the MRI/MRA.

Study burden and risks

For participating patients there is no additional risk.
CTA, MRI/MRA and DSA are routine everyday investigations. DSA will only be performed if the CTA and the MRI/MRA have not shown the cause of the ICH, to prevent unnecessary exposure to the -albeit small- risk of the procedure.

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

Patients with spontaneous intracerebral haemorrhage (ICH) between 18 and 70 years of age.

Exclusion criteria

Patients between 45 and 70 years with a known history of hypertension and ICH in the thalamus, putamen, or posterior fossa will be excluded, as well as patients on oral anticoagulants with an INR greater than 2.5 and patients who will not be able to undergo (one of) the examinations because of contraindications.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	14-07-2008
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	01-07-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-09-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-09-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-01-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-01-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-09-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL21285.041.08

Study results

Date completed: 13-07-2015

Actual enrolment: 0

Summary results
Trial is onging in other countries