Time course of cerebral perfusion and vasospasm in patients with and without development of DCI after SAH: establishing threshold values.

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1) To unravel the pathogenesis of DCI by studying the time course of cerebral perfusion and vasospasm in patients with aneurysmal SAH with CT, and 2) to obtain a diagnostic tool for the detection of DCI on the basis of CT-perfusion (CTP) parameters...

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

Summary

ID

NL-OMON30914

Source
ToetsingOnline

Brief title
Delayed Cerebral Ischemia: Diagnostic Evaluation/DECIDE

Condition

- Central nervous system vascular disorders
- Aneurysms and artery dissections

Synonym
secondary ischemia, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Veni-subsidie

Intervention

Keyword: cerebral ischemia, perfusion, subarachnoid hemorrhage, vasospasm

Outcome measures

Primary outcome

The primary outcome is the occurrence of DCI. This outcome will be studied with

the following study parameters: cerebral perfusion, degree of vasospasm,

ischemic changes.

Secondary outcome

not applicable

Study description

Background summary

Patients with aneurysmal subarachnoid haemorrhage (SAH) are at risk for delayed cerebral ischaemia (DCI). This complication increases the risk for morbidity and case fatality by 3 times and occurs in approximately one third of SAH patients. Despite many years of research the pathogenesis of DCI is still unclear and a diagnostic test for presence of DCI is lacking. Vasospasm has traditionally been thought to be the main causative factor for DCI. Since only 60% op patients with vasospasm develop DCI other factors must play a role. With novel computed tomography (CT) techniques the perfusion of brain tissue can be visualised and measured. Data on brain perfusion and its relation with vasospasm can give new insight in the development of DCI. Eventually diagnosis and treatment of DCI could be improved on the basis of these new insights.

Study objective

1) To unravel the pathogenesis of DCI by studying the time course of cerebral perfusion and vasospasm in patients with aneurysmal SAH with CT, and
2) to obtain a diagnostic tool for the detection of DCI on the basis of

CT-perfusion (CTP) parameters and degree of vasospasm.

Study design

This study is a prospective cohort study in which 250 SAH patients with and without DCI will be compared. To study the pathogenesis, the time course of cerebral perfusion and vasospasm will be assessed in the first 150 patients. In this same group threshold values for the diagnosis of DCI will be established for perfusion parameters and vasospasm. These threshold values will then be validated in the next 100 patients.

Study burden and risks

Included patients will undergo a maximum of three additional CT scans. The risk of cancer caused by the additional radiation is 0,5 x10-3 times higher than normal. Due to adequate exclusion criteria there is no risk of contrast-induced nephropathy (CIN) in this study. The risk of contrast media induced severe acute general reactions is 0.04% per patient. Patients at risk for adverse reactions will be excluded.
Clarifying the pathogenesis of DCI and the development of diagnostic criteria will contribute to better diagnosis and treatment of DCI in future patients.

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

18 years of age or older
Aneurysmal subarachnoidal hemhorrage (SAH)
Admission within 72 hours after SAH

Exclusion criteria

Acute general reactions to or contra-indications for the admission contrast CT-scan
Impaired renal function (serum creatinin > 200umol/l)
Pregnancy
Diabetes Mellitus

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-05-2008
Enrollment:	250
Type:	Actual

Medical products/devices used

Generic name:	Nonionic contrast agent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-11-2007
Application type:	First submission
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	NL17943.041.07