Tilburg Copeptin in aSAH patients Study

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The aim of this prospective study is to elucidate whether copeptin could be used as a marker for prognosis and severity of aSAH in a Dutch intensive care population?

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

Summary

ID

NL-OMON38452

Source
ToetsingOnline

Brief title
TCSS

Condition

- Central nervous system vascular disorders

Synonym
aSAH, cerebral haemorrhage

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Er is geen externe vergoeding voor deze studie.

Intervention

Keyword: aSAH, Copeptin, Outcome

Outcome measures

Primary outcome

One year poor fuctional outcome measured by the Glasgow Outcome Sclae (GOS 1-3).

Secondary outcome

Development of vasospasm, case fatility 30 days after admission, mortality after one year, functional outcome 12 months after aSAH, assessed by the Glasgow Outcome Scale and modified Ranking Scale.

Study description

Background summary

Subarachnoid haemorrhage from a ruptured cerebral aneurysm (aSAH) is a significant cause of mortality and morbidity throughout the world. Multiple clinically grading scales are developed to indicate the severity of neurological injury, and to provide prognostic information regarding outcome. However, prediction of outcome remains difficult and complicates decision making for active treatment. Copeptin, the C-terminal part of the arginine vasopressin precursor peptide, is associated with the severity and outcome of critical illness. Recently it has been reported that initial high levels of plasma copeptin are highly predictive for poor outcome and vasospasm in patients presenting with aSAH in the Chinese population.

Study objective

The aim of this prospective study is to elucidate whether copeptin could be used as a marker for prognosis and severity of aSAH in a Dutch intensive care population?

Study design

A single center prospective observational study

Study burden and risks

one extra laboratory sample taken and a questionary after one year
No extra risks

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

* Admission to the intensive care of the St. Elisabeth Hospital Tilburg
* Age 18 year or over
* Start clinical symptoms of SAH within 24hr of at admission to the hospital.
AND
* Informed consent to participate in the trial
* Aneurysm confirmed by computerized tomography angiography (CT-A) with or without digital substraction angiography (DSA).
* Blood drawn after obtaining informed consent on the first 24 hours of admission at de ICU.

Exclusion criteria

* Less than 18 years of age
* Severe language barrier, unable to read the informed consent
* SAH due to non- aneurysmal causes
* Recent ischemic or hemorrhagic stroke
* Recent intracerebral hemorrhage without subarachnoid blood
* Recent previous head trauma
* recent acute myocardial infarction (AMI)
Chronic heart failure
* recent acute exacerbation of COPD (AECOPD)
Chronic liver cirrhosis
Recent acute pancreatitis
Recent sepsis/septic shock

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2013
Enrollment:	133
Type:	Actual

Ethics review

Approved WMO

Date:	12-09-2013
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22580
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45096.008.13
OMON	NL-OMON22580