Study with Copeptin as predictor of outcome in patients with a subarachnoid haemorrhage from a ruptured cerebral aneurysm.

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Could copeptin be used as a marker for prognosis and severity of aSAH in Dutch intensive care populations?

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22580

Bron
Nationaal Trial Register

Verkorte titel
TCSS

Aandoening

Subarachnoid haemorrhage from a ruptured cerebral aneurysm, aSAH, delayed cerebral ischaemia, DCI.

Ondersteuning

Primaire sponsor: Intensive Care
St. Elisabeth Hospital Tilburg
Hilvarenbeekseweg 60
5022 GC Tilburg
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Overige ondersteuning: self-financing research

fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective is to investigate the ability of copeptin to predict poor one-year functional outcome, GOS 1-3, in patients with aneurysmal SAH in the Dutch population.

Toelichting onderzoek

Achtergrond van het onderzoek

SUMMARY
Background

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 copeptin in blood are highly predictive for poor outcome and vasospasm in patients presenting with aSAH in the Chinese population.

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 Dutch intensive care populations?

Study design

A single center prospective observational study

Study population

Patients admitted to the ICU of the St. Elisabeth Hospital with an age of 18 years or over with clinical symptoms of SAH within 24 hours at admission in which a cerebral aneurysm is confirmed by computerized tomography angiography (CT-A) with or without digital substraction angiography (DSA).

Intervention

After informed consent is obtained blood will be drawn in an serum tube of 5 ml on the first 24 hours of admission at de ICU for copeptin levels in the aSAH group. Included aSAH patients will be evaluated for delayed cerebral ischaemia (DCI). 30 days and 12 months after the aSAH, alive patients will be contacted by the research nurse for a questionnaire by telephone, including the Glasgow Outcome Scale (GOS) and the modified Ranking Scale (mRS). In a control group of 30 healthy volunteers without cardiovascular risk factors and without any neurological deficits of copeptin levels will be estimated to compare these results with the copeptin levels of the included aSAH patients.

Main outcome measurement

Poor one-year functional outcome, GOS 1-3, development of DCI, case fatality 30 days after admission, one year mortality and functional outcome 12 months after aSAH, assessed by both Glasgow Outcome Scale and the modified Ranking Scale.

Doel van het onderzoek

Could copeptin be used as a marker for prognosis and severity of aSAH in Dutch intensive care populations?

Onderzoeksopzet

30 days and 12 months after the aSAH, the general practitioner of the patient will be contacted to check whether the patient is still alive. After 12 months alive patients will be contacted by the research nurse for a questionnaire by telephone.

Onderzoeksproduct en/of interventie

For copeptin levels in the aSAH group, blood will be drawn in an extra serum tube of 5 ml on the first 24 hours of admission at the ICU.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Admission to the intensive care of the St. Elisabeth Hospital Tilburg.

Age 18 year or over.

Start clinical symptoms of SAH within 24hr at admission.

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 (< 30 days).

Recent intracerebral hemorrhage without subarachnoid blood (< 30 days).

Existing recent head trauma (< 30 days).
Recent acute myocardial infarction (AMI)(< 30 days).

Chronic heart failure.

Recent acute exacerbation of COPD (AECOPD) (< 30 days).

Recent sepsis/septic shock (< 30 days).

Recent acute pancreatiits (< 30 days).

Liver cirrhosis.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2013
Aantal proefpersonen:	103
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	15-08-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38452
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3952
NTR-old	NTR4118
CCMO	NL45096.008.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38452

Resultaten

Samenvatting resultaten
none