CO2 reactivity in the acute stage of aneurysmal subarachnoid hemorrhage.

Published: 24-02-2009
Last updated: 11-05-2024

•What is the prognostic value of CO2 reactivity compared to standard TCD measurements to predict the occurrence of DCI in patients with SAH?•Does magnesium therapy change CO2 reactivity after SAH?

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

Summary

ID

NL-OMON37010

Source
ToetsingOnline

Brief title
CO2 reactivity after subarachnoid hemorrhage

Condition

- Central nervous system vascular disorders

Synonym
hemorrhage between the brain membranes, subarachnoid hemorrhage

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: De onderzoeker ontvangt subsidie van de Nederlandse Hartstichting;subsidienummer 2005BO16

Intervention

Keyword: cerebral autoregulation, delayed cerebral ischemia, magnesium, subarachnoid hemorrhage, vasospasm

Outcome measures

Primary outcome

1. Occurrence of delayed cerebral ischemia, defined by a persisting clinical

deterioration (i.e. new focal deficit, decrease in consciousness, or both) with

no evidence for rebleeding or hydrocephalus on CT and no other medical causes,

such as infections or metabolic disturbances, and with or without hypodensity

on CT.

2. Occurrence of a disturbed CO2R test

Secondary outcome

Occurrence of radiographic vasospasm and perfusion parameters on CT-P

Study description

Background summary

An important complication after subarachnoid hemorrhage (SAH) is delayed cerebral ischemia (DCI), that is responsible for poor outcome (death or dependency on activities for daily life) in one third of patients. Currently, the additional prophylactic benefit of magnesium sulphate therapy is studied in a randomized controlled clinical trial (MASH-II, METC nr NL17943.041.07). Accurate prediction of DCI is however still not possible. The prognostic value of vasospam on trancranial doppler (TCD) is diappointing to predict the occurrence of DCI. Besides vasospasm, a disturbed cerebral autoregulation is also indicated as a contributing factor in the pathophysiology of DCI. A non-invasive technique to determine cerebral reactivity is measuring the response of CO2 inhalation with TCD. There are indications that CO2 reactivity (CO2R) has a better predictive value for DCI than standard TCD measurements. This has not yet been studied in a larger patient population and optimal

cut-off points remain unclear. There are also indications that magnesium therapy reduces the amount of TCD detected vasospam, but the effect on cerebral vasoreactivity is unknown. Prediction and a better understanding of DCI is important to allow for better therapautic oppurtunities in the future.

Study objective

•What is the prognostic value of CO2 reactivity compared to standard TCD measurements to predict the occurrence of DCI in patients with SAH?

•Does magnesium therapy change CO2 reactivity after SAH?

Study design

This is a prospective diagnostic cohort study and will be imbedded in the DECIDE study (METC nr NL17943.041.07), that studies the pathogenesis of DCI with CT-perfusion parameters.

Study burden and risks

TCD is a non-invasive and painless procedure that is part of daily standard patient care in many centers worldwide. The CO2R test performed during the TCD will take approximately 10 minutes. Side effects associated with CO2 inhalation are minimal and transient. Side effects can be agitation, anxiety, dizziness or headache. When a patient reports such a side effect the CO2 inhalation will be stopped immediately. Temporarily increased intracranial pressures have also been described, but always normalized after cessation of the CO2 inhalation. No adverse neurological or other medical complications due to the test were described. We do not monitor intracranial pressure routinely, as this is a very invasive procedure.
As this is a diagnostic study, no direct benefits are expected for the participating patients. The extra monitoring of the patients due to this study could lead in some cases to the early detection of abnormalities and a suited intervention. For future patients, the benefit is a better understanding, prediction and therefore treatment of DCI.

Contacts

Public
Academisch Medisch Centrum

Heidelberglaan 100
3584 CX Utrecht
Nederland

Scientific
Academisch Medisch Centrum

Heidelberglaan 100
3584 CX Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Aneurysmal subarachnoid hemorrhage
Inclusion within 3 days after the hemorrhage
Aged 18 years or older
Informed consent obtained

Exclusion criteria

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

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2008
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	24-02-2009
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	20-05-2011
Application type:	Amendment
Review commission:	METC NedMec

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	NL23336.041.08