Induced hypertension for delayed cerebral ischaemia after aneurysmal subarachnoid haemorrhage: a feasibility study

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To assess the feasibility of a randomized clinical trial on induced hypertension, and to assess whether the studied intervention is effective in increasing CBF.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON35291

Source
ToetsingOnline

Brief title
Induced hypertension for DCI after SAH

Condition

- Central nervous system vascular disorders

Synonym
"intra-cerebral haemorrhage"; "brain haemorrhage"

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Hersenstichting Nederland;nummer

2009(1)-72

Intervention

Keyword: DCI, hypertension, SAH

Outcome measures

Primary outcome

1. To test whether it is feasible to perform a multicentre randomised

controlled trial on induced hypertension to

improve neurological outcome after SAH.

Secondary outcome

1. Number of patients experiencing DCI as a proportion of the total amount of

SAH patients.

2. Reasons for exlusion

3. Number of patients (in retrospective) with other causes of neurological

deterioration.

4. Difference in cerebral haemodynamics between the intervention groups.

5. Neurological condition at the start and end of the study period.

6. Neurological condition at 6 weeks after SAH.

7. Number of complications and adverse events.

Study description

Background summary

Delayed cerebral ischaemia (DCI) is a major complication after aneurysmal subarachnoid hemorrhage (SAH). The proportion of SAH patients who develop DCI is around 30%. DCI is associated with a 1.5-3 fold higher mortality rate. Many centers around the world use induced hypertension, alone or in combination with

haemodilution and hypervolaemia, so called Triple-H, as standard therapy in the treatment of DCI, but the efficacy of induced hypertension in reducing DCI is based on case series only, and not on a randomized clinical trial.

Study objective

To assess the feasibility of a randomized clinical trial on induced hypertension, and to assess whether the studied intervention is effective in increasing CBF.

Study design

Multi-centre, randomized, controlled feasibility trial

Intervention

1. No intervention (reference group)
2. Induced hypertension: increasing the mean arterial pressure with a maximum of 30 mmHg with norepinephrine. In addition, the maximum MAP in these patients will be 140 mmHg and the maximum systolic blood pressure 240 mmHg. The maximum dosage of norepinephrine will be 1000 ng/kg/minute. If there is no clnical improvement observed with 24 hours after reaching one of the above mentioned maximum values the admisnitration of norepinephrine will be tapered.

Study burden and risks

Patients are randomized between 2 treatment groups. The medical and nursing staff in this unit has large experience with induced hypertension and the patient will be monitored continuously. All patients will have two perfusions CT*s

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

1. Admission to the hospital
2. Age 18 years or over
3. Aneurysmal SAH, demonstrated on CT-angiography or cerebral agiograph, with onset less than 72 hours before admission
4. Glascow Coma Sum Score above 8.
5. DCI (decrease of 2 GSC points or all new neurological focal deficits), diagnosed by a neurologist, neurosurgeon or intensivist within 3 hours after deterioration.
6. Informed consent

Exclusion criteria

1. Symptomatic cerebral aneurysm not yet treated by coiling or clipping
2. Co-existing severe head injury.
3. A history of a cardiac rhythm disorder, necessitating medical treatment.
4. A history of a left ventricular pump failure, necessitating medical treatment.
5. Pregnancy.
6. Known allergy for CT-contrast agents.
7. Renal failure, defined as a serum creatinine > 150 µmol/l
8. Other causes cause for neurological deterioration (see page 15 of the study protocol for the differential diagnosis)
9. Severe hypertension, defined as a MAP of 120 mmHg or higher

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2009
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	29-07-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-03-2010
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	NL22603.041.08