Acetazolamide as a treatment after hemorrhagic stroke

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23709

Source
Nationaal Trial Register

Brief title
ASH

Health condition

aneurysmal subarachnoid hemorrhage

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

Cerebral perfusion (arterial spin labeling (ASL) MRI) on day 7±2 after ictus.

Secondary outcome

Cerebral perfusion (arterial spin labeling (ASL) MRI) on day 12±2 after ictus.

Serious adverse events (SAEs) and serious unexpected serious adverse reactions (SUSARs) until 10 weeks after ictus.

The occurrence of DCI. DCI will be defined as either “clinical deterioration or cerebral infarction due to delayed cerebral ischemia”.

Study description

Background summary

Approximately 30% of patients with subarachnoid hemorrhage (SAH) suffer from delayed cerebral ischemia (DCI). This in-hospital complication increases the risk of poor functional outcome. The only available drug that reduces the risk of DCI is nimodipine. However, the effect of nimodipine is only modest. Acetazolamide, a carbonic anhydrase inhibitor, could be a useful additional drug for the prevention of DCI by acting on 3 different pathways: (1) it increases cerebral blood flow via vasodilation, (2) it decreases brain edema through carbonic anhydrase inhibition, and (3) it decreases cerebrospinal fluid production. These combined actions of acetazolamide make it a promising drug for the prevention of DCI in patients with SAH. In a phase II study we will evaluate safety and proof-of-concept of acetazolamide in patients with aneurysmal SAH. The primary aim of this study is to evaluate whether acetazolamide improves cerebral perfusion as measured with magnetic resonance imaging (MRI) performed 7±2 days after ictus. The secondary objectives of this study are to investigate (1) the safety of acetazolamide when given until day 14 after aneurysmal SAH (aSAH), (2) whether acetazolamide improves cerebral perfusion also at day 12±2 after ictus, (3) whether the proportion of patients with DCI is lower in the intervention group. The tertiary objectives of this study are: (1) to investigate whether acetazolamide improves the Quality of Life score and modified Rankin Scale (degree of disability) at 10 weeks after SAH, and (2) to examine whether the proportion of patients with hydrocephalus is lower in the intervention group.

Study objective

In a phase II study we will evaluate safety and proof-of-concept of acetazolamide in patients with aneurysmal SAH. The primary aim of this study is to evaluate whether acetazolamide improves cerebral perfusion as measured with magnetic resonance imaging (MRI) performed 7±2 days after ictus.

Study design

day 7±2 after ictus, day 12±2 after ictus, 10 weeks after ictus

Intervention

In the intervention group, subjects will receive acetazolamide intravenously as well as

treatment as usual. The dosage of acetazolamide will be similar to the average dosage used for the treatment of intracranial hypertension: 1.5 grams per day in three dosages of 0.5 grams in a 100 mL solution per dose. The intervention will be initiated within 72 hours after ictus, after aneurysm securing, and it will be continued until day 14 after ictus in addition to the usual treatment. The control group will not receive any study medication and will only receive treatment as usual.

Contacts

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Eligibility criteria

Inclusion criteria

≥18 years old

Aneurysm confirmed by the presence of subarachnoid blood by computed tomography (CT) or lumbar puncture and by visualization of the aneurysm on either CT angiography, MR angiography or digital subtraction angiography

Hospital arrival ≤72 hours of ictus

Eligible for aneurysm coiling

Exclusion criteria

Intensive care (IC) required for >72 hours after ictus (i.e., during inclusion window)

Perimesencephalic bleeding

Traumatic SAH

Severe liver dysfunction or severe renal dysfunction

Allergic reaction for sulfomides

Any contraindication for MR imaging (e.g. metal objects within or around the body)

Pregnancy or women who are breastfeeding

Addison’s disease

Phenytoin use

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2017
Enrollment:	40
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 02-03-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50004
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6493
NTR-old	NTR6680
CCMO	NL60773.041.17
OMON	NL-OMON50004

Study results