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Effect of simvastatin on endothelial dysfunction, fibrinolysis, coagulation and inflammation after aneurysmal subarachnoid hemorrhage

Submission date
29/06/2006

Recruitment status
No longer recruiting

Registration date
29/06/2006

Overall study status
Completed

Last Edited
02/09/2009

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M.D.I. Vergouwen

Contact details
Academisch Medisch Centrum
Afdeling Neurologie H2
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31 (0)20 5663842
m.d.vergouwen@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR668

Study information

Scientific Title

Study objectives
In patients with aneurysmal subarachnoid hemorrhage (SAH), simvastatin restores endothelial cell damage, activates fibrinolysis, and improves coagulation and inflammation after the hemorrhage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised doube blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Aneurysmal subarachnoid hemorrhage

Interventions
Patients will receive simvastatin 80 mg a day or placebo until day 14 after aneurysmal subarachnoid hemorrhage.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Simvastatin

Primary outcome measure
1. The effects of simvastatin on the parameters of fibrinolysis, coagulation, inflammation and endothelial function after SAH
2. The relation between changes in fibrinolytic activity and endothelial cell damage and activation

Secondary outcome measures
1. The occurrence of cerebral ischemia after SAH
2. Outcome on the Glasgow Outcome Scale and Academic Medical Center Linear Disability Scale (ALDS) three and six months after subarachnoid hemorrhage
3. The relation between vasospasm as observed on transcranial Doppler examination and parameters of fibrinolysis, coagulation, endothelium dysfunction and inflammation
4. The relationship between cerebral ischemia as observed on perfusion CT-scans and parameters of fibrinolysis, coagulation, endothelium dysfunction and inflammation
5. The relationship between plasminogen activator inhibitor type-1(PAI-1) polymorphism and fibrinolysis in patients treated with simvastatin and placebo
6. The relationship of polymorphisms in the endothelin system on endothelial cell damage
7. Differences in cerebral microcirculation between patients treated with placebo and simvastatin

Overall study start date
01/05/2006

Completion date
01/11/2007

Eligibility

Key inclusion criteria
1. Patients with clinical symptoms and signs of SAH with an aneurysmal bleeding pattern on the initial computerised tomography (CT) scan. CT scan has to be performed within 48 hours after SAH onset
2. Patients with a perimesencephalic hemorrhage pattern on the initial CT scan while computed tomographic angiography (CTA) or conventional angiography has shown an appropriate aneurysm. CTA or angiography has to be performed within 48 hours after SAH onset
3. If CT scan is negative while there is evidence of bleeding in the cerebrospinal fluid (xanthochromia) and the CT-angiography has shown an aneurysm

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Key exclusion criteria
1. Under 18 years of age
2. A time lapse of more than 48 hours after SAH onset
3. Patients using aspirin or warfarin
4. Patients already using statins
5. Contra-indication for simvastatin (active liver disease, liver transaminase more than three times the normal upper limit, myopathy)
6. Kidney insufficiency
7. If death appears imminent
8. Pregnancy or lactation

Date of first enrolment
01/05/2006

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academisch Medisch Centrum
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Department of Neurology
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
University/education

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
University/education

Funder Name
Academic Medical Centre (AMC) (Netherlands) - Department of Neurology

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2009		Yes	No