Medication therapy in aneurysmatic cerebral haemorrhage.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27006

Source
NTR

Brief title
TRAASA

Health condition

Aneurysm
Subarachnoid haemorrhage/hemorrhage
Tranexamic acid, Cyklokapron
Acetylsalicylic acid, Aspirin

Aneurysma
Subarachnoidale bloeding
Tranexaminezuur
Acetylsalicylzuur, Aspirine

Sponsors and support

Primary sponsor: Germans, M.R.
Coert, B.A.
Source(s) of monetary or material Support: Germans, M.R.

Intervention

Outcome measures

Primary outcome

Modified Rankin Scale.

Secondary outcome

1. In hospital possible or definite rebleed and interval with first haemorrhage;

2. Rebleed during endovascular or surgical treatment;

3. Thromboembolic events during endovascular treatment;

4. (Micro)infarctions on MR-imaging after treatment and after 6 months;

5. Hemorrhagic complications (intra and extracranial);

6. Extracranial thrombosis;

7. Treatment for hydrocephalus (lumbar puncture, lumbar or ventricular drainage);

8. Hemorrhagic complications with neurological deficit after placement of an extraventricular drain.

Study description

Background summary

Approximately one fourth of all patients with subarachnoid hemorrhage (SAH), due to a ruptured intracranial aneurysm, have an unfavourable outcome and approximately 50% die due to the hemorrhage or subsequent complications.
There are several major causes for this course, such as inhospital rebleed in 8-11% which mainly occurs within the first 6 hours after the initial hemorrhage. Half of these patients die during hospital admission and when surviving, develop more severe cognitive dysfunction than patients without a rebleed. Endovascular treatment is becoming a more standard procedure of a ruptured aneurysm because of generally better outcome. Nevertheless, it is also associated with complications, such as thromboembolic events (11%) and aneurysm rerupture (4,1-7,6%). These complications attribute to an additional 13% risk of unfavourable outcome or death. Another major cause, occurring in upto one third of all aneurysmatic subarachnoid hemorrhages, is development of delayed ischemic neurological deficit (DIND) between the third and fourteenth day after the initial bleeding which leads to secondary ischemia. This phenomenon causes disability or death in 13-22% of all patients. The etiology has not been elucidated yet, but some authors think that platelet aggregation may play a

role in the development of secondary ischemia.
Many studies are performed to improve the outcome of these patients by reducing trombolytic activity before or reduce platelet activation during or after treatment of the aneurysm. Systematic reviews of these studies showed trends towards better outcome but no significant results. A drawback in the included studies is that the majority was performed in the twentieth century when outcome of subarachnoid hemorrhage was worse because of less specialised institutes, lacking the use of nimodipine and less patients treated with endovascular methods. Therefore more recently, studies have been done with improved treatment protocols for antifibrinolytic or antiplatelet therapy and these tend to show better results than experienced in the past.
With the current evidence, we developed a new treatment protocol which tries to reduce the above mentioned complications by combining the optimal medication regimen in every single step in the course of this disease.

Study objective

Improvement of favourable outcome by consecuetive treatment of tranexamic acid before aneurysm treatment with switch to acetylsalicylic acid short before start of treatment and continued for two weeks.

Study design

Modified Rankin Scale: 6 months

Secondary outcomes:

1. Until aneurysm treatment;

2. During aneurysm treatment;

3. During endovascular treatment of aneurysm;

4. After aneurysm treatment within 72 hours after primary haemorrhage and after six months;

5. During admission.

Intervention

1. Group one: placebo administered intravenous in ten minutes, every four hours until four to eight hours preceding planned intervention followed by placebo every 24 hours until two weeks after aneurysm treatment;

2. Group two: 1 gram TA administrated intravenous in ten minutes, followed by a same dose every four hours until four to eight hours preceding planned intervention. In case of endovascular treatment, between ending TA and until at least two hours before aneurysm

treatment start of 300 mg ASA, and continue every 24 hours until two weeks after aneurysm treatment. In case of planned surgical treatment an identical dosage ASA is started six hours after operation, continued every 24 hours until two weeks after aneurysm treatment.

Both groups undergo MR-imaging after aneurysm treatment within 72 hours after the primary haemorrhage, and after six months with an interview to assess the modified Rankin Scale.

Contacts

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Eligibility criteria

Inclusion criteria

1. Aneurysmatic SAH less than 48 hours ago;

2. Age 18 years and older;

3. Informed consent.

Exclusion criteria

1. Presence of deep vein thrombosis;

2. History of blood coagulation disorder;

3. Use of antiplatelet or anticoagulation medication during haemorrhage;

4. Immediate neurosurgical intervention necessary (with the exception of ventricular drainage);

5. Contraindication for use of aspirin;

6. Pregnancy;

7. Thrombocytopenia (<100 x 109/L) at admission;

8. Severe renal (serum creatinin >150 mmol/L) or liver failure (AST > 150 U/l or ALT > 150 U/l or AF > 150 U/l or ã-GT > 150 U/l);

9. Imminent death within 24 hours.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2009
Enrollment:	300
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL1595
NTR-old	NTR1675
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A