Ultra-early tranexamic acid after subarachnoid hemorrhage.

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Patients with subarachnoid hemorrhage (SAH) treated by standard, state-of-the-art SAH management with additional ultra-early and short-term TXA administration (TXA group) have significantly more often a favourable outcome after six months (score 0-3…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22386

Bron
NTR

Verkorte titel
ULTRA

Aandoening

subarachnoid hemorrhage
intracerebral hemorrhage
subarachnoidale bloeding
hersenbloeding

Ondersteuning

Primaire sponsor: Academic Medical Center
Meibergdreef 9
1105 AZ Amsterdam
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Overige ondersteuning: Currently we are raising funds.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Modified Rankin Scale score dichotomized as a favourable (0-3) or unfavourable (4-6) outcome.

Toelichting onderzoek

Achtergrond van het onderzoek

Approximately 50% of all patients with an subarachnoid hemorrhage (SAH) dies due to the hemorrhage or subsequent complications. There are several major causes for this course, such as in-hospital rebleed in 4-12% which most frequently occurs within the first 6 hours after the primary hemorrhage (“ultra-early rebleed”). Half of the patients with a rebleed die during hospital admission and when they survive, they develop more severe cognitive dysfunctions. Reducing the rebleeds by ultra-early administration of tranexamic acid (TXA) could be a major factor in improving the functional outcome after SAH.

Study design:

Multicenter, prospective, randomized trial with blind endpoint assessment.

Study population:

Adult patients (18 years and older) included within 24 hours after SAH.

Primary and secondary outcomes:

Primary: Dichotomized outcome at the Modified Rankin Scale after six months (0-3: favourable; 4-6: unfavourable).

Secondary: Case fatality rate, rebleed rate, thromboembolic complications, delayed cerebral ischemia rate, complications (hydrocephalus, thromboembolic events, extracranial thrombosis or hemorrhagic complications), care costs.

Intervention:

Group one: Standard treatment with additional administration of 1 g TXA intravenously in ten minutes, immediately after the diagnosis SAH, succeeded by continuous infusion of 1 g per 8 hours until a maximum of 24 hours.

Group two: Standard treatment with no TXA administration.

Main study parameters/endpoints:

Primary: Modified Rankin Scale score after six months, dichotomized into favourable and unfavourable outcome.

Secondary: Rebleed and case fatality rate, complications during the first six months after hemorrhage and infarctions on MR-imaging at six months.

Doel van het onderzoek

Patients with subarachnoid hemorrhage (SAH) treated by standard, state-of-the-art SAH management with additional ultra-early and short-term TXA administration (TXA group) have significantly more often a favourable outcome after six months (score 0-3 on the Modified Rankin Scale) compared to a patients treated by standard, state-of-the-art SAH management without additional TXA administration (control group).

Onderzoeksopzet

Primary outcome: Six months after SAH.

Secondary outcomes:

1. Six months after SAH;

2. Before or during aneurysm treatment;

3. During endovascular treatment;

4. During admission.

Onderzoeksproduct en/of interventie

TXA group:

Standard treatment with additional administration of 1 g TXA intravenously in ten minutes, immediately after the diagnosis SAH, succeeded by continuous infusion of 1 g per 8 hours until a maximum of 24 hours.

Control group:

Standard treatment with no TXA administration.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Admission to one of the study centers or their referring hospitals;

2. CT-confirmed SAH with ictus less than 24 hours ago;

3. Age 18 years and older;

4. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. No loss of consciousness after the hemorrhage with WFNS grade 1 or 2 on admission in combination with a perimesencephalic hemorrhage;

2. Bleeding pattern on CT compatible with a traumatic SAH;

3. Treatment for deep vein thrombosis;

4. History of blood coagulation disorder;

5. Pregnancy or breastfeeding;

6. 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);

7. Imminent death within 24 hours.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2013
Aantal proefpersonen:	950
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-01-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3122
NTR-old	NTR3272
CCMO	NL20120125
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A