Effect of dexamethasone (DXM) therapy in patients with a brain bleed: A comparision of a non-operative treatment versus surgery on patient recovery.

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The study is designed to prove a superior effect of surgery (by BHC) on functional outcome compared to DXM therapy.

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

Samenvatting

ID

NL-OMON21208

Bron
NTR

Verkorte titel
DECSA

Aandoening

EN: Chronic subdural hematoma, CSDH, dexamethasone, DXM

NL: Chronisch subduraal hematoom, dexamethason

Ondersteuning

Primaire sponsor: Department of Neurosurgery and Neurology
Haaglanden Medical Centre, The Hague
Overige ondersteuning: No funding applicable.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main primary endpoint in is the functional outcome, as expressed by mRS, in both treatment arms at 3 months.

Toelichting onderzoek

Achtergrond van het onderzoek

A chronic subdural haematoma (CSDH) is a common neurological disease with a rapidly rising incidence due to increasing age and widespread use of anticoagulants. Surgical intervention by burr hole craniotomy (BHC) is the current standard practice for symptomatic patients. In several hospitals however, dexamethasone (DXM) therapy is used as a non-surgical alternative, because of possible complications, a recurrence rate up to 30% and mortality associated with surgery. Efficacy of DXM treatment however has yet to be proven in high quality comparison studies by means of a randomized-controlled trial. In addition, beneficial effects of DXM treatment are believed to have a slow onset, in contrast to BHC that drains the hematoma and thus causes immediate relief. The objective of this study is to compare the effect of DXM therapy versus primary surgery on functional outcome in symptomatic patients with CSDH.

Doel van het onderzoek

The study is designed to prove a superior effect of surgery (by BHC) on functional outcome compared to DXM therapy.

Onderzoeksopzet

Patients will be evaluated (neurological examination, modified Rankin Score, mRS, Markwalder Grading Score, MGS) at:

- Baseline (day of presentation)

- Discharge

- 2 weeks (combined with follow up CT)

- 3 months (at the outpatient clinic)

- 6 months (by phone) by filling in a questionnaire regarding quality of life (short form 36 heath questionnaire) and mRS grading by phone.

Onderzoeksproduct en/of interventie

Intervention arm: Patients in the intervention (DXM) arm will receive DMX in a daily dosage of 16 mg (8 mg every 12 hours) on day 1 to 4. Thereafter, DXM will be tapered down by halve every 3 days (4 mg every 12 hours on day 5 to 7, 2 mg every 12 hours on day 8 to 10, 1 mg every 12 hours on day 11 to 13, 0.5 mg every 12 hours on day 14 to 16 and 0.5 mg once a day on day 17 to 19). DXM is administered orally in tablets or intravenously when oral administration is not possible due to the clinical condition of the patient. Subjects in the DXM arm will be treated concomitantly with a proton pump inhibitor (Esomeprazole, 40 mg daily) prophylactic, during the DXM treatment regimen.

Control arm: Participants randomized to the control arm will receive operative treatment by burr hole craniostomy (BHC) with insertion of a subdural drain for 48 hours (as this is standard clinical practice). The surgical procedure (BHC) will be performed according to the current in hospital neurosurgical BHC-protocol (which is identical in all 3 participating neurosurgical hospitals). General or local anaesthesia will be applied, depending on the discretion of the treating neurosurgeon which form will be the safest. After evacuation of the hematoma in the surgical theatre, a subdural drain will be inserted for 48 hours.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1) Presence of a chronic subdural haematoma

2) Clinical symptoms must correlate to the cerebral lesion

3) Severity of symptoms must be MGS 1-3

4) Subject must be 18 years or older.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1) an acute subdural haematoma

2) pregnancy

3) known hypersensitivity to DXM

4) known ulceration in the gastro-intestinal tract,

5) uncontrolled diabetes mellitus (DM) defined as a HbA1C value > 8% (64 mmol/mol)

6) clinical suspicion of an acute systemic infection (fever, leucocytosis, elevated C-reactive protein (CRP)

7) history of gastro-intestinal bleeding

8) glaucoma

9) previous history of severe affective disorders on steroids (i.e. psychosis)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	170
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-10-2016
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	NL6046
NTR-old	NTR6185
Ander register	EudraCT: 2015-001563-39 : ABR: NL56666.098.16

Resultaten

Samenvatting resultaten
In preparation: Manuscript regarding protocol publication.