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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21208

Source
NTR

Brief title
DECSA

Health condition

EN: Chronic subdural hematoma, CSDH, dexamethasone, DXM

NL: Chronisch subduraal hematoom, dexamethason

Sponsors and support

Primary sponsor: Department of Neurosurgery and Neurology
Haaglanden Medical Centre, The Hague
Source(s) of monetary or material Support: No funding applicable.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary outcomes include: clinical outcome at discharge, 2 weeks and at 6 months (expressed by mRS and MGS), the number of surgical intervention prevented in the DXM group, quality of life (as expressed by the Short Form – 36 Health Survey, SF-36) at 6 months, haematoma thickness after 2 weeks, haematoma recurrence (defined as recurrence of symptoms and neurological signs after initial improvement with persistence, recurrence or increase of CSDH on follow up cranial CT) during the first 6 months, complications and drug related adverse events, mortality, duration of hospital stay and health care costs in both subject groups.

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

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.

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2016
Enrollment:	170
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-10-2016
Application type:	First submission

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	NL6046
NTR-old	NTR6185
Other	EudraCT: 2015-001563-39 : ABR: NL56666.098.16

Study results

Summary results
In preparation: Manuscript regarding protocol publication.