Randomized Evaluation of Surgery in Elderly with Traumatic Acute SubDural Hematoma

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

Samenvatting

ID

NL-OMON27007

Bron
NTR

Verkorte titel
RESET-ASDH

Aandoening

Traumatic Brain Injury, Acute Subdural Hematoma

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: BeNeFIT grant (ZonMw & KCE)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To establish the effect of early surgical hematoma evacuation compared to conservative treatment on functional outcome (as expressed by the GOS-E) after 1 year in elderly patients with a traumatic ASDH.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The rapidly increasing number of elderly (≥ 65 years old) with traumatic brain injury (TBI) is accompanied by substantial medical and economic consequences. An intracranial hematoma, specifically an acute subdural hematoma (ASDH), is the most common injury in elderly with TBI. The surgical versus conservative treatment of this patient group remains an important clinical and moral dilemma, since it is in most cases unclear which treatment leads to a better outcome for the patient. Current guidelines are not based on high-quality evidence and compliance is low, allowing for large treatment variation in both Belgium and the Netherlands for patients with a traumatic ASDH. In addition, elderly are underrepresented in scientific TBI literature and are therefore not included in current guidelines or prognostic models, leading to major uncertainty in (neurosurgical) decision-making for this group. As participants in two large TBI research projects (CENTER-TBI, Net-QuRe), the investigators observe that the uncertainty regarding treatment of elderly with a traumatic ASDH will not be solved by the current ongoing studies. Therefore, they recognize the necessity of undertaking a prospective, randomized, multicenter trial on the (cost-)effectiveness of early surgical hematoma evacuation versus a conservative treatment in elderly with a traumatic ASDH.
Objective: To compare the (cost-)effectiveness of early surgical hematoma evacuation versus a conservative treatment in elderly patients with a traumatic ASDH.
Study design: A prospective, pragmatic, multicenter, randomized controlled trial (RCT).
Study population: Patients ≥ 65 years with at first presentation a GCS ≥ 9 and a traumatic ASDH >10 mm or a traumatic ASDH <10 mm and a midline shift >5 mm, or a GCS < 9 with a traumatic ASDH <10 mm and a midline shift <5 mm without extracranial explanations for the comatose state, for whom clinical equipoise exists regarding the preferred treatment.
Intervention: Patients are randomized to either early surgical hematoma evacuation (A) or conservative management on the ICU or the ward (B). In case of neurological deterioration during conservative management, delayed surgery can be performed. The exact neurosurgical technique will be left to the discretion of the surgeons.
Main study parameters/endpoints: Functional outcome after 1 year, expressed by the rating on the Extended Glasgow Outcome Scale (GOS-E)
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Both treatment strategies are already used in current clinical practice as standard medical care. Therefore, there are no extra risks for patients participating in the study compared to patients outside the study. Study participation adds a minimal burden of three follow-up evaluations by visit in the first year (at 3, 6 and 12 months) and subsequent yearly evaluations by phone or postal until five years after the injury. Future elderly patients with a traumatic ASDH will benefit mostly from this study’s results.

Doel van het onderzoek

The authors hypothesize that early neurosurgical hematoma evacuation generally leads to a better functional outcome (GOS-E) and is more cost-effective compared to conservative management, although subgroups may be identified for which the latter is the preferred treatment strategy.

Onderzoeksopzet

Admission, discharge, 3 months, 6 months, 1 year, 2 years, 3 years, 4 years, 5 years

Onderzoeksproduct en/of interventie

Early neurosurgical hematoma evacuation

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥ 65 years
- A GCS of ≥ 9 and a traumatic ASDH >10 mm in diameter or a traumatic ASDH <10 mm but with a midline shift >5 mm, or a GCS <9 and a traumatic ASDH <10 mm and a midline shift <5 mm without extracranial explanations for the comatose condition

- Clinical equipoise exists (i.e. the responsible neurosurgeon is uncertain about the benefits of either treatment)
- Informed consent is obtained or deferred

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Additional epidural hematoma (EDH) or infratentorial (e.g. cerebellar) intracerebral hemorrhage (ICH)
- Major traumatic abdominal or thoracic injury (each separately defined as an Abbreviated Injury Scale (AIS) score ≥ 4) or a ‘moribund’ state at presentation (e.g. bilaterally absent pupillary responses)
- Known terminal condition resulting in a life expectancy of less than 1 year

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-10-2020
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	30-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52833
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9012
CCMO	NL72116.058.20
OMON	NL-OMON52833

Resultaten