Randomized Evaluation of Surgery in Elderly with Traumatic Acute SubDural Hematoma

No registrations found.

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

Summary

ID

NL-OMON27007

Source
NTR

Brief title
RESET-ASDH

Health condition

Traumatic Brain Injury, Acute Subdural Hematoma

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: BeNeFIT grant (ZonMw & KCE)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

- Functional outcome as expressed on the GOS-E besides the one year measurement (this includes mortality)
- Disease-specific quality of life as expressed on the QOLIBRI
- Health-related quality of life as expressed on the EuroQol-5D-5L
- Cognitive functioning as expressed on the MOCA
- Direct & indirect costs
- Duration of hospital stay
- Time from event to surgery
- Discharge locations
- Complications (during hospital stay)
- Secondary surgery in both groups

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

Early neurosurgical hematoma evacuation

Contacts

Public
LUMC Leiden
Ranjit Singh

+31682548283
Scientific
LUMC Leiden
Ranjit Singh

+31682548283

Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

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):	25-10-2020
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	30-10-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52833
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results