

Revised Evaluation of Surgery in Elderly with Traumatic Acute SubDural Hematoma (RESET-ASDH study)

Survival and quality of life after early surgical intervention versus wait-and-see in elderly patients with a traumatic acute subdural hematoma (ASDH): an international multicenter prospective cohort study

Published: 19-06-2020

Last updated: 19-03-2025

To compare the (cost-)effectiveness of early surgical hematoma evacuation versus a conservative treatment in elderly patients with a traumatic ASDH.

| | |
|------------------------------|---|
| Ethical review | Approved WMO |
| Status | Pending |
| Health condition type | Central nervous system vascular disorders |
| Study type | Observational non invasive |

Summary

ID

NL-OMON52833

Source

ToetsingOnline

Brief title

RESET-ASDH

Condition

- Central nervous system vascular disorders

- Nervous system, skull and spine therapeutic procedures
- Vascular haemorrhagic disorders

Synonym

Traumatic acute subdural hematoma / Traumatic intracranial bleeding

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: BeNeFIT Belgium-Netherlands Funding of International Trials (samenwerkingsverband tussen ZonMw en KCE)

Intervention

Keyword: Elderly, Neurotrauma, Subdural hematoma, Traumatic brain injury

Outcome measures

Primary outcome

Functional outcome after 1 year, expressed by the rating on the Extended

Glasgow Outcome Scale (GOS-E)

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

The rapidly increasing number of elderly (≥ 55 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 an international, prospective, multicenter observational study on the (cost-)effectiveness of early surgical hematoma evacuation versus a conservative treatment in elderly with a traumatic ASDH.

Study objective

To compare the (cost-)effectiveness of early surgical hematoma evacuation versus a conservative treatment in elderly patients with a traumatic ASDH.

Study design

An international, prospective, multicenter, observational study.

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.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Age \geq 55 years
 - History of traumatic brain injury
 - Acute subdural hematoma $>10\text{mm}$ and/or with a midline shift* $>5\text{mm}$ on radiological imaging (CT-scan)
- * Midline shift will be measured as the perpendicular distance between the septum pellucidum and a line designated the midline on CT-scan in brain setting.

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 \geq 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
- Severe and progressive dementia or cerebral infarction necessitating daily care in a nursing home in the pre-trauma period

Study design

Design

| | |
|---------------------|---------------------------------|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

Recruitment

| | |
|---------------------------|-------------|
| NL | |
| Recruitment status: | Pending |
| Start date (anticipated): | 01-11-2022 |
| Enrollment: | 300 |
| Type: | Anticipated |

Ethics review

Approved WMO

Date: 19-06-2020

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO

Date: 20-10-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO

Date: 16-03-2021

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO

Date: 30-08-2022

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO

Date: 12-06-2023

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27007

Source: NTR

Title:

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL72116.058.20 |
| OMON | NL-OMON27007 |