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Six, twelve or twenty-four hours of drainage after the evacuation of chronic bleeding on the brain's surface?

Submission date
02/12/2020

Recruitment status
No longer recruiting

Registration date
16/12/2020

Overall study status
Completed

Last Edited
02/02/2026

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A chronic subdural haematoma (CSDH) is a serious condition where blood collects between the skull and the surface of the brain. It's frequently caused by a head injury. These liquified clots most often occur in patients age 60 and older. The treatment is brain surgery with evacuation of the blood collection using a borehole in the cranium and placement of a drain to empty the remaining blood in the period after the operation.
This is a national study involving all neurosurgical departments in Denmark. We investigate the optimal drain period using either 6, 12 or 48 hours of drainage following an operation for CSDH.

Who can participate?
Patients older than 18 years, free of other brain diseases or history of previous brain surgery

What does the study involve?
This study involves patients admitted to any hospital in Denmark with a CSDH and randomizes patients to receive either 6, 12 or 24 hours of drainage following their surgery for CSDH.

What are the possible benefits and risks of participating?
No additional benefits or risks.

Where is the study run from?
Odense Universitetshospital (Denmark)

When is the study starting and how long is it expected to run for?
November 2019 to June 2024

Who is funding the study?
Odense Universitetshospital (Denmark)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Postoperatively drainage in 6, 12 or 24 hours after burr-hole evacuation of chronic subdural hematoma - a national randomised controlled trial

Acronym
DRAINTIME2

Study objectives
Current study hypothesis as of 13/10/2021:
Previous study hypothesis:
Drainage time of 6 and 12 hours is non-inferior to drainage time of 24 hours regarding recurrence rate. We hypothesize that the shortest possible drainage time is associated with fewer drain-related complications, faster mobilization, shorter hospital stays and thus greater economic impact on the overall health service burden.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/08/2020, Scientific Ethical Committee of Copenhagen (Regionhuset, Damhaven 12, 7100 Vejle, Denmark; +45 76638221; komite@rsyd.dk), ref: S-20200044

Primary study design
Interventional

Study design

National, multicenter, randomized controlled non-inferiority trial with three parallel arms using a multi-arm, multi-stage (MAMS) design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Preventing prolonged immobilisation due to presence of a subdural drain after evacuation of chronic subdural hematoma

Interventions
Current interventions as of 13/10/2021:
The DRAIN TIME 2 study is a Danish, national, multicenter, randomized controlled non-inferiority trial with three parallel arms. The arms correspond to 6, 12, and 24 hours drainage, where the former two arms are experimental arms and the latter 24h group is the common control arm. Online randomization with a 1:1:1 allocation using a web-based randomization software within Redcap will be performed to randomise participants to a drainage period of 6, 12, or 24 hours post-operatively.

The trial uses a multi-arm, multi-stage (MAMS) design, which enables adaptive reductions of the number of experimental arms considered during the course of the trial. The applied design is described in Bratton et al (2013). Our trial is organized in five stages. After each stage, non-inferiority of both arms is tested during an interim-analysis at stage-specific significance levels. Significant arms continue to the next stage, whereas non-significant arms can be dropped (non-binding). The final non-inferiority test decision takes place after the final stage (or as soon as both experimental arms are stopped) and uses all available data. Interim and final analyses rely on the same primary outcome as well as the same non-inferiority margin.

Patients are discharged home or to a local hospital when they no longer need specialized neurosurgical care, and when the hospital is ready to receive them. Routine postoperative CT will not be carried out.

This trial follows Danish standard clinical care and treatment, published by DACHSUHS. Placement of a subdural drain is standard treatment, and only deviation is the drainage time. Routinely, blood samples are obtained at admission. In the sub-study, extra blood is collected and stored. Also, CSDH fluid and the surrounding membrane are removed during surgery. In the sub-study this biological material is collected and stored for later analyses, in addition with fluid collected from the drain in post-operative period.
Three months after the operation, patients were followed-up for recurrent symptomatic CSDH, death and complications, including thromboembolic events following the surgery.

Previous interventions:
Patients will be randomized to a drainage period of 6, 12 or 24 hours post-operatively.

Included and consented patients will be randomized using a web-based randomization software within Redcap.

Patients are discharged home or to a local hospital when they no longer need specialized neurosurgical care, and when the hospital is ready to receive them. Routine postoperative CT will not be carried out.

This trial follows Danish standard clinical care and treatment, published by DACHSUHS. Placement of a subdural drain is standard treatment, and only deviation is the drainage time. Routinely, blood samples are obtained at admission. In the sub-study, extra blood is collected and stored. Also, CSDH fluid and the surrounding membrane are removed during surgery. In the sub-study this biological material is collected and stored for later analyses, in addition with fluid collected from the drain in post-operative period.
Three months after the operation, patients were followed-up for recurrent symptomatic CSDH, death and complications, including thromboembolic events following the surgery.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome measure as of 13/10/2021:
Recurrence rate at 90 days measured using modified Rankin Scale (mRS) at 90 days followup

Previous primary outcome measure:
At 3 months post-operatively.
1. Recurrence rate measured using mRS

Key secondary outcome(s)
Current secondary outcome measures as of 13/10/2021:
1. Mortality rate at 90 days measured using patient records at 90 days follow-up
2. Disability measured using the modified Rankin Scale (mRS) at 90 days follow-up
3. Patient-reported health status of patients measured using The Short Form (36) Health Survey during admission and at 90 days follow-up
4. Number of hours post-surgery before the patients are mobilized out of bed measured using patient records during admission
5. Length of hospital stay measured as the length of patient stay at the department of neurosurgery before being discharged to home or transferred to another hospital using patient records during admission
6. Drain-related complications such as bleeding, pain, general discomfort, and infection measured by observation by a physician after removal of the drain
7. Complications related to immobilization such as back pain, deep venous thrombosis and/or pulmonary embolism, and constipation measured using patient records at 90 days follow-up

Sub-analyses of patients with recurrence at 90 days follow-up:
1. Co-morbidities, medications, age, gender, and evaluation of hematoma subtypes on CT from admission (homogenous, separated, mixed, or membranous) will be collected using patient records at 90 days follow-up

Previous secondary outcome measures:
1. Number of patients who have died at 3 months measured using patient records
2. Disability measured using the Modified Rankin Scale at 3 months
3. Health status of patients measured using The Short Form (36) Health Survey (during admission and again after 3 months)
4. Number of hours post-surgery before the patients are mobilized out of bed measured using patient records
5. Length of hospital stay (stay at department of neurosurgery before discharged to home of transferred to another hospital) measured using patient records
6. Drain-related complications such as bleeding, pain, general discomfort, infection measured by

observation by a physician just after removal of the drain
7. Complications related to immobilization (backpain, deep venous thrombosis and/or pulmonary embolism, constipation) measured using patient records at 3 month follow up
8. In patients with recurrence at 3 months measured using patient records:
8.1. Co-morbidities
8.2. Medications
8.3. Age
8.4. Gender
8.5. Evaluation of hematoma subtypes on CT from admission (homogenous, separated, mixed, or membranous)

Completion date
01/06/2024

Eligibility

Key inclusion criteria
1. Adult patients (aged ≥18 years)
2. Minimum 2 weeks since known head trauma
3. Patients with symptomatic CSDH confirmed on CT or magnetic resonance imaging (MRI), admitted to a neurosurgical department for operative treatment
4. Patients undergoing a single burr-hole evacuation and placement of a passive subdural drain

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients with abnormalities in their cerebrospinal fluid
2. Patients with changes or abnormalities in their normal cerebrospinal fluid dynamics, e.g. ventricular peritoneal shunt
3. Patients with additional intracranial pathology that requires neurosurgical treatment
4. Patients with recurrent CSDH or with previous craniotomy or other transcranial surgery

Date of first enrolment
01/03/2021

Date of final enrolment
01/03/2024

Locations

Countries of recruitment
Denmark

Study participating centre
Odense University Hospital
J. B. Winsløws Vej 4
Odense
Denmark
5000

Study participating centre
Rigshospitalet
Blegdamsvej 9
Copenhagen
Denmark
2100

Study participating centre
Aarhus University hospital
Palle Juul-Jensens Blvd. 161
Aarhus
Denmark
8200

Study participating centre
Aalborg University Hospital
Hobrovej 18-22
Aalborg
Denmark
9100

Sponsor information

Organisation
Odense University Hospital

ROR
https://ror.org/00ey0ed83

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Odense Universitetshospital

Alternative Name(s)
Svendborg Sygehus, Odense University Hospital, OUH

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Denmark

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/06/2024	17/06/2024	Yes	No
Protocol article		14/03/2022	02/02/2026	Yes	No
Participant information sheet			04/01/2021	No	Yes
Participant information sheet			04/01/2021	No	Yes
Protocol file			04/01/2021	No	No