

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

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
02/12/2020	No longer recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
16/12/2020	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
02/02/2026	Surgery	

## 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?

Dr Mads Hjortdal Grønhøj, mads.groenhoej@rsyd.dk

# Contact information

## Type(s)

Scientific

## Contact name

Dr Mads Hjortdal Grønhøj

## Contact details

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

Nil known

# 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

## **Study design**

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

## **Primary study design**

Interventional

## **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 or 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  $\geq 18$  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?

<a href="#"><u>Results article</u></a>	12/06/2024	17/06/2024	Yes	No
<a href="#"><u>Protocol article</u></a>	14/03/2022	02/02/2026	Yes	No
<a href="#"><u>Participant information sheet</u></a>		04/01/2021	No	Yes
<a href="#"><u>Participant information sheet</u></a>		04/01/2021	No	Yes
<a href="#"><u>Protocol file</u></a>		04/01/2021	No	No