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24 or 48 hours of drainage after operation for a blood collection on the brain's surface

Submission date	Recruitment status	[ ] Prospectively registered
20/10/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/10/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/11/2020	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A subdural haematoma is a serious condition where blood collects between the skull and the surface of the brain. It's usually caused by a head injury. A chronic subdural hematoma (SDH) is an old clot of blood on the surface of the brain beneath its outer covering. These liquefied clots most often occur in patients age 60 and older who have brain atrophy, a shrinking or wasting away of brain tissue due to age or disease.
This is a national study involving all neurosurgical departments in Denmark. We investigate 24 versus 48 hours of drainage following an operation for chronic subdural hematoma (CSDH).

Who can participate?
Patients age 60 or above who presented with a symptomatic CSDH

What does the study involve?
Patients will be randomly allocated to receive either 24 or 48 hours of drainage following the operation to remove the CSDH. Three months after the operation, patients are followed-up.

What are the possible benefits and risks of participating?
No immediate benefits, but findings will benefit future patients.
As the optimal drainage period is not known, we see no risk of participating.

Where is the study run from?
The study is run from all neurosurgical departments in Denmark.

When is the study starting and how long is it expected to run for?
September 2017 to May 2022

Who is funding the study?
Neurosurgical Department of Rigshospitalet, Copenhagen (Denmark)

Who is the main contact?
Thorbjørn Søren Rønn Jensen, tjens07@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Twenty-four versus 48 hours drainage after burr hole evacuation of chronic subdural hematoma: A national randomized controlled study

Acronym
24vs48CSDH

Study objectives
24 versus 48 hours of closed passive subdural drainage after single burr hole evacuation of chronic subdural hematoma are equal regarding recurrent hematomas and death.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 05/03/2018, Scientific Ethical Committee of Copenhagen (Regionhuset, Damhaven 12, 7100 Vejle, Denmark; +45 76638221; komite@rsyd.dk), ref: S-20180010

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files (in Danish)

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

Interventions
Participants were randomized to either 24 or 48 hours of closed, subdural, passive drainage following a single burr hole evacuation of a chronic subdural hematoma (CSDH).

After the operation for CSDH, the patient was registered in the Research Electronic Data Capture (Redcap) and assessed by either a member of DACSUHS or the attending neurosurgeon for inclusion within the first 24 hours. Included and consented patients were randomized using a web-based randomization software within Redcap. A closed envelope stating the time for drain removal was kept at the patient's bed and opened 24 hours postoperative by the nursing staff. The drain was either removed or kept for an additional 24 hours according to randomization. As such, the randomization was blinded to the patient, the nursing staff, and physicians on the ward and both groups of patients received identical care for 24 hours.

Patients were discharged home or to a local hospital when they no longer needed specialized neurosurgical care, and when the hospital was ready to receive them. Routine postoperative CT was not carried out.
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 measure
Recurrent hematomas within 90 days measured using patient records

Secondary outcome measures

Death within 90 days measured using patient records

Overall study start date
01/09/2017

Completion date
01/05/2022

Eligibility

Key inclusion criteria
Patients age 60 or above who presented with a symptomatic CSDH proven by computed tomography or magnetic resonance

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
420

Total final enrolment
420

Key exclusion criteria
1. Previous intracranial surgery and known head injury within the last 14 days prior to surgery
2. Patients treated with craniotomy, multiple burr holes, subgaleal drain placement and if the drain was removed prior to study inclusion by either the patient or hospital staff
3. Patients unable to give formal consent

Date of first enrolment
01/09/2018

Date of final enrolment
01/07/2020

Locations

Countries of recruitment
Denmark

Study participating centre

Rigshospitalet
Blegdamsvej 9
Copenhagen
Denmark
2100

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

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
Rigshospitalet

Sponsor details
Department of Neurosurgery
Opgang 6, 3. sal
Inge Lehmanns Vej 6
Copenhagen
Denmark
2100
+45 35456031
Morten.Ziebell@regionh.dk

Sponsor type
Hospital/treatment centre

Website
https://www.rigshospitalet.dk/afdelinger-og-klinikker/neuro/hjerne-og-nervekirurgi/Sider/default.aspx

ROR
https://ror.org/03mchdq19

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Rigshospitalet

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Denmark

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/11/2020	No	Yes