

Are chronic subdural haematoma best treated with simple evacuation or evacuation and external drainage?

Submission date
13/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
26/07/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
06/10/2009

Condition category
Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Acronym

CaCSH trial

Study objectives

There is no difference in the recurrence of chronic subdural haematomas (CSDH) regardless of whether post-operative drainage or no drainage is used.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Cambridge Local Ethics Research Committee in October 2004, reference number: 04/Q0108/52

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Chronic subdural haematoma (CSDH)

Interventions

Closed subdural-to-external drainage for 48 hours after completion of a standard burr hole evacuation of the CSDH evacuation versus burr holes and drainage with no external drain

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Recurrence rate after drainage of CSDH as measured by re-operations

Secondary outcome measures

1. Operative complications
2. Medical complications
3. Length of hospitalisation
4. Neurological status and modified Rankin scale at discharge and at three-months follow up

Overall study start date

01/11/2004

Completion date

31/12/2008

Eligibility**Key inclusion criteria**

Symptomatic chronic subdural haematoma in adult patients

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200 subjects in either arm

Key exclusion criteria

1. Patients younger than 18 years
2. Treatment other than burrhole required (e.g. craniotomy)
3. Drainage of an ipsilateral CSDH within preceding six months

Date of first enrolment

01/11/2004

Date of final enrolment

31/12/2008

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre
Box 167
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation

Addenbrooke's Hospital, Cambridge University Hospitals (UK)

Sponsor details

Box 166
Academic Department of Neurosurgery
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 2QQ

Sponsor type

Government

ROR

<https://ror.org/055vbx86>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Addenbrooke's Hospital, Cambridge University Hospitals (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/09/2009		Yes	No