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A randomised, double blind, placebo-controlled trial of a two-week course of dexamethasone for adult patients with a symptomatic Chronic Subdural Haematoma (Dex-CSDH trial)

Submission date
07/11/2014

Recruitment status
No longer recruiting

Registration date
07/08/2015

Overall study status
Completed

Last Edited
18/09/2024

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Chronic subdural haematoma (CSDH) is a collection of liquefied blood between the surface of the brain and its outmost lining. It is especially common in older individuals and can happen with only a minor injury to the head. It can cause drowsiness, confusion, limb weakness and problems with mobility. In the UK, 5,000 people aged over 65 years are diagnosed with a CSDH each year. In the NHS, patients with severe symptoms usually undergo an operation to evacuate the CSDH. Patients with milder symptoms are usually actively monitored. Although about 80-85% of the patients tend to recover well from this operation, approximately 15-20% of patients will have a recurrence of the CSDH and require a further operation. This significantly reduces the chances of good recovery. A considerable body of evidence suggests that steroids can reduce the rate of recurrence and, in some cases, avoid the need for surgery altogether. However, steroids have side effects and it is not known whether the benefits outweigh the risks in this context. Currently, there is no high-quality evidence showing whether steroids should be used routinely for patients with CSDH. The Dex-CSDH study will provide this much needed evidence. The Dex-CSDH study will focus on symptomatic patients with CSDH and will compare the use of steroids against placebo ('dummy' treatment).

Who can participate?
All patients admitted to a participating neurosurgical unit with a CSDH will be considered for the study based on pre-specified criteria.

What does the study involve?
Once consent is in place, you will be assigned randomly (like the flip of a coin) to take either dexamethasone or placebo. The latter is sometimes called the ‘dummy capsule’. It looks the same as the active treatment (dexamethasone) but does not contain any of the active ingredients. The treatment (dexamethasone or placebo) will be administered daily for 14 days on a tapering course, which reduces the dose over the 14-day study period. Neither you nor your doctor will know which treatment you are receiving – this is necessary in order to draw valid

conclusions at the end of the study. Before you leave the hospital we will assess your level of recovery. We will also ask you to fill in a short questionnaire pack at 3 and 6 months after leaving the hospital, as we would like to find out about your recovery and state of health.

What are the possible benefits and risks of participating?
There is no guaranteed benefit from taking part in this study. However, information collected in the study may benefit patients with a subdural haematoma in the future. Apart from the potential side effects of dexamethasone, there are no additional risks or disadvantages involved with taking part in this study. Dexamethasone is a medication used regularly in the treatment of many medical conditions. It is also widely used in many patients with conditions affecting the nervous system, e.g. brain tumours. The side effects of dexamethasone are rare with a short course such as the one in this study. You will continue to receive the standard care for your condition.

Where is the study run from?
The study is run from the University of Cambridge and Cambridge University Hospitals NHS Foundation Trust. It is expected that the majority of UK neurosurgical centres will participate.

When is the study starting and how long is it expected to run for?
September 2014 to August 2019 (updated 09/06/2020, previously: May 2020 (as of 04/10/2018))

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK).

Who is the main contact?
Prof Peter Hutchinson – Chief Investigator
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Contact information

Type(s)
Scientific

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Clinical Trials Information System (CTIS)
2014-004948-35

Protocol serial number
HTA 13/15/02

Study information

Scientific Title
A randomised, double blind, placebo-controlled trial of a two-week course of dexamethasone for adult patients with a symptomatic Chronic Subdural Haematoma (Dex-CSDH trial)

Acronym
Dex CSDH

Study objectives
Dexamethasone can improve the functional outcome of patients with symptomatic chronic subdural haematomas by reducing the rate of surgical intervention and the recurrence rate.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/131502

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Haydock, 14/04/2015, REC ref: 15/NW/0171

Primary study design
Interventional

Study design
Randomised double-blind placebo-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic subdural haematoma CSDH

Interventions
Patients will be randomized to take either dexamethasone or a placebo. The treatment will be administered daily for up to 14 days on a tapering course, which reduces the dose over the study period. The study period lasts for 6 months. At 3 months and again at 6 months short questionnaires will be completed, either face to face, by post or via telephone, to assess level of recovery.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dexamethasone

Primary outcome(s)
Modified Rankin Scale (mRS) at 6 months post-randomisation

Key secondary outcome(s)
Current secondary outcome measures as of 26/08/2020:
Measured using patient records unless noted otherwise:
1. Number of CSDH-related surgical interventions undertaken during the index admission
2. Number of CSDH-related surgical interventions undertaken during subsequent admissions in the follow-up period
3. Glasgow Coma Scale (GCS) at discharge from NSU and at 6 months
4. mRS score at discharge from NSU and at 3 months
5. Barthel Index at discharge from NSU, 3 months and 6 months
6. Mortality (30-day and 6 months)
7. EuroQOL (EQ-5D) at discharge from NSU, 3 months and 6 months
8. Length of stay in NSU
9. Discharge destination from NSU
10. Length of stay in secondary care
11. Health-economic analysis
12. Adverse Events

(added 21/09/2020)
13. Post-operative recurrence is a tertiary outcome measure and is defined as a symptomatic recurrence requiring re-operation of a previously evacuated ipsilateral chronic subdural hematoma

Previous secondary outcome measures:
1. Rate of cSDH-related surgical interventions undertaken during the index admission
2. Rate of cSDH-related surgical interventions undertaken during subsequent admissions
3. Glasgow Coma Scale (GCS) at discharge from NSU and 6 months
4. mRS score at discharge from NSU and 3 months
5. Barthel Index at discharge from NSU, 3 months and 6 months
6. Mortality (30-day and 6 months)

Completion date
29/08/2019

Eligibility

Key inclusion criteria
1. Informed consent
2. Adults aged 16 or older
3. Symptomatic cSDH confirmed on cranial imaging (predominantly hypodense or isodense crescentic collection along the cerebral convexity on CT)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Total final enrolment
748

Key exclusion criteria
1. Patients who have already undergone surgical intervention for a cSDH during the same index admission
2. Condition with conditions where steroids are clearly contra-indicated (i.e. active infections)
3. Already on steroids
4. Enrolment in same study within last 12 months
5. Time interval from the time of admission to NSU to initiation of trial medication exceeds 72 hours
6. cSDH in presence of CSF shunt

Date of first enrolment
11/08/2015

Date of final enrolment
24/11/2018

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
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CB2 0QQ

Study participating centre
Imperial College Healthcare NHS Trust, London
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Study participating centre
Royal Victoria Infirmary
Newcastle upon Tyne

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Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust and University of Cambridge

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/12/2020	17/12/2020	Yes	No
Results article		01/03/2024	18/09/2024	Yes	No
Protocol article	protocol	04/12/2018		Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	statistical analysis plan	10/12/2019	12/12/2019	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes