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Randomised evaluation of surgery with craniectomy for uncontrollable elevation of intracranial pressure

Submission date
12/09/2005

Recruitment status
No longer recruiting

Registration date
21/11/2005

Overall study status
Completed

Last Edited
07/06/2022

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Following injury to the head, the brain, just like any other part of the body, becomes bruised and swollen. This swelling occurs in the confines of the rigid skull and results in an increase in pressure and reduction in blood and oxygen supply to the brain.
Treatment in the intensive care unit is directed at controlling swelling and pressure and maintaining a good blood and oxygen supply to the brain. There are a number of conventional treatments that are used to achieve this, including the ventilator to support breathing and various drugs to support blood pressure and reduce swelling directly. Whilst these treatments are effective in some patients, others with more severe swelling are at an increased risk.
Currently there are two advanced methods to control brain swelling. The first is the use of an operation called a decompressive craniectomy. In this operation a part of the skull bone is removed (front or side) leaving the brain protected by the membranes and scalp. This creates an opening for the brain, helping to control swelling and high pressure. The opening is later repaired using the original bone or a synthetic plate. The second available method is to use strong drugs to control the activity in the brain. The benefit of each of these treatments, and which method is more effective for a particular type of patient, are currently unclear. This study is being conducted to try to find out which is the best method of treatment. We to enrol approximately 400 participants around the world (200 in the group receiving the operation to control the swelling and 200 in the group receiving medical treatment with stronger drugs).

Who can participate?
Participants must have sustained a head injury, be between the ages of 10 and 65 years, with an abnormal CT scan requiring intra-cranial pressure (ICP) monitoring and raised ICP that has not been successfully managed by the initial medical treatment.

What does the study involve?
If the patient requires these more advanced measures to control pressure and swelling, they will be randomly allocated to one of two groups: either the operation to control the swelling or advanced medical treatment. If either treatment is not effective, then the alternative treatment can be provided. A computerised tomography (CT) scan, which uses x-rays and a computer to

create detailed images of the inside of your body, will be taken on admission to hospital and before random allocation to one of the two groups (randomisation). These scans are considered routine for this type of injury and pose no additional risk. At 6, 12 and 24 months following the head injury, you will be contacted in order to complete a questionnaire to assess your recovery. This will be done either by post, a telephone call or in the out patient clinic. The questionnaire takes approximately 30 minutes to complete.

What are the possible benefits and risks of participating?
If you chose to participate in the study, or allow your relative to, there may or may not be any direct benefit. Both treatments are considered to be standard treatments for this condition and are used routinely. It is hoped that the information gained from this study can be used in the future to benefit other people with similar conditions.

Where is the study run from?
Cambridge University and Cambridge University Hospitals Foundation Trust, UK.
See participating centres on the study website http://www.rescueicp.com/frameset4.html

When is the study starting and how long is it expected to run for?
The study recruited its first patient in January 2004 and has a projected completion date of December 2014.

Who is funding the study?
National Institute of Health Research (NIHR) and the Medical Research Council (MRC), UK.

Who is the main contact?
Mr Peter Hutchinson
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Randomised Evaluation of Surgery with Craniectomy for Uncontrollable Elevation of Intra-Cranial Pressure trial

Acronym
RESCUEicp

Study objectives
The application of decompressive craniectomy (as a last-tier therapy) to head-injured patients with raised intracranial pressure (ICP) refractory to medical treatment results in improvement in outcome:
1. Decompressive craniectomy results in an improvement in the Extended Glasgow Outcome Score compared to optimal medical treatment
2. Decompressive craniectomy results in an improvement in surrogate endpoint measures (including specific outcome measures [36-item Short Form questionnaire], control of ICP, time in intensive care and time to discharge from the neurosurgical unit) compared to optimal medical treatment

More detailed information on the protocol can be found at http://www.rescueicp.com /downloads.html

Ethics approval required
Old ethics approval format

Ethics approval(s)
Eastern MREC, 22/10/2003, ref: 03/5/059

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe traumatic brain injury

Interventions
Decompressive craniectomy (surgical procedure) versus maximal medical management (including barbiturates).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measures as of 23/05/2016:
Extended Glasgow Outcome Scale (GOSE) at 6 months after randomisation

Previous primary outcome measures:
Assessment of outcome at discharge (Glasgow Outcome Score) and 6 months (Extended Glasgow Outcome Score)

Key secondary outcome(s))
Current secondary outcome measures as of 23/05/2016:
1. GOSE at 12 and 24 months after randomisation
2. Mortality at 6, 12 and 24 months after randomisation
3. SF-36 and SF-10 (below 16 years) questionnaires at 6, 12 and 24 months after randomisation
4. Glasgow Coma Scale (GCS) at discharge from neurosciences hospital
5. Assessment of ICP control
6. Time in intensive care
7. Time to discharge from the neurosciences hospital
8. Detailed health-economic analysis
Adverse events will also be reported.

Secondary outcome measures from 18/10/2012 to 23/05/2016:
1. EGOS at 12, 24 and 36 months
2. SF 36 at 6, 12 and 24 months with a health economic analysis

Original secondary outcome measures until 18/10/2012:
1. Assessment of outcome using the 36-item short form (SF-36) questionnaire
2. Assessment of ICP control
3. Time in intensive care
4. Time to discharge from the neurosurgical unit

Completion date
31/03/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 23/05/2016:
1. Patients with head injury
2. Age 10-65 years
3. Abnormal CT scan requiring ICP monitoring with raised ICP (>25mmHg >1 – 12 hours) refractory to initial medical treatment measures
4. Patients may have had an immediate operation for a mass lesion but not a 'decompressive' craniectomy

Previous inclusion criteria:
1. Patients aged 10 - 65 years, either sex
2. An abnormal computed tomography (CT) scan of the head
3. Requiring ICP monitoring with raised ICP (greater than 25 mmHg greater than 1 - 12 hours), refractory to initial medical measures
4. Patients may have an immediate operation for a mass lesion but not a decompressive

craniectomy
5. Patients who are immunologically, hepatically or renally compromised can be included, but type and extent of their impairment are noted

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Current exclusion criteria as of 23/05/2016:
1. Bilateral fixed and dilated pupils
2. Bleeding diathesis
3. Devastating injury not expected to survive for 24 hours and follow up not possible
4. Patients treated by the Lund protocol are also not eligible

Previous exclusion criteria:
1. Bilateral fixed and dilated pupils
2. Bleeding diathesis
3. A devastating injury not expected to survive for 24 hours
4. Follow-up not possible
5. Unable to monitor ICP
6. Patients treated on the Lund protocol
7. Primary decompression
8. Have received barbiturates pre-randomisation
9. Brainstem involvement

Date of first enrolment
01/01/2004

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
United Kingdom

England

Brazil

Canada

China

Czech Republic

Germany

Greece

Italy

Japan

Latvia

Malaysia

Peru

Russian Federation

Saudi Arabia

Singapore

Spain

Türkiye

United States of America

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Addenbrooke's Hospital (UK)

ROR
https://ror.org/055vbxf86

Funder(s)

Funder type
Research organisation

Funder Name
Academy of Medical Sciences (UK)

Alternative Name(s)
The Academy of Medical Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
The Health Foundation (UK)

Funder Name
MRC managed by NIHR on behalf of the MRC-NIHR partnership (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/09/2016		Yes	No
Results article	secondary analysis	06/06/2022	07/06/2022	Yes	No
Protocol article	protocol	01/10/2006		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	statistical analysis plan	01/10/2016		No	No

Study website	Study website	11/11/2025	11/11/2025	No	Yes