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Multi-centre prospective randomised trial of early decompressive craniectomy in patients with severe traumatic brain injury

Submission date
16/06/2005

Recruitment status
No longer recruiting

Registration date
21/07/2005

Overall study status
Completed

Last Edited
04/10/2016

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Traumatic brain injury is a potentially devastating injury that mainly affects young males. About 10% of patients admitted with severe traumatic brain injury have a diffuse injury (over a widespread area) and persistent brain swelling that is difficult to control with medical treatment. Over the past decade, treatment of these patients has been shifting from barbiturate coma (a temporary coma) to decompressive craniectomy. This is a well-established surgical procedure in which a large piece of skull bone is removed, stored for 1-2 months and then replaced. The aim of this study is to assess the effectiveness of this procedure in patients with severe traumatic brain injury.

Who can participate?
Patients aged 15-60 with severe diffuse traumatic brain injury

What does the study involve?
Participants are randomly allocated to be treated with either the best medical care or decompressive craniectomy and best medical care. They are followed up to assess the outcome 6 months later.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
A number of hospitals in Australia, New Zealand, Saudi Arabia, Canada and the USA participated in the study with the lead site being the Alfred Hospital in Melbourne, Australia

When is the study starting and how long is it expected to run for?
August 2003 to June 2011

Who is funding the study?
National Health & Medical Research Council, the Victorian Trauma Foundation, Victorian

Neurotrauma Initiative, Transport Accident Commission, Intensive Care Foundation, and the Western Australian Institute of Medical Research

Who is the main contact?
Prof. Jamie Cooper
J.Cooper@alfred.org.au

Contact information

Type(s)
Scientific

Contact name
Prof Jamie Cooper

Contact details
Intensive Care
The Alfred
Commercial Road
Melbourne
Australia
3004
+61 (0)3 92071806
J.Cooper@alfred.org.au

Additional identifiers

Study information

Scientific Title
Multi-centre prospective randomised trial of early decompressive craniectomy in patients with severe traumatic brain injury

Acronym
DECRA

Study objectives
Study hypothesis:
That early decompressive craniectomy will improve long term neurological outcome in patients with severe traumatic brain injury and intracranial hypertension which is refractory to conventional management.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Alfred Human Research Ethics Committee, 27/06/2002, ref: 68/02

Primary study design

Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Interventions
Early decompressive craniectomy versus best current medical management

Intervention Type
Procedure/Surgery

Primary outcome(s)
Glasgow Outcome Score (GOSE) measured 6 months after the injury. Proportion (%) of Favourable Outcomes (GOSE 5-8) is the primary outcome measure.

Key secondary outcome(s)
1. Mean and maximum hourly ICP
2. Favourable outcomes (GOSE 5-8) at 12 months post injury
3. Mean GOSE at 6 and 12 months using ordinal logistic regression
4. Mortality - hospital, 6 months, 12 months
5. Days in intensive care unit (ICU) and hospital

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Age 15-60 years
2. First 72 hours from time of injury
3. Severe diffuse Traumatic Brain Injury defined as:
3.1. Glasgow Coma Score (GCS) <9 and computed tomography (CT) scan with any evidence of brain swelling. CT brain scan DII + some evidence of swelling or DIII or DIV
OR
3.2. GCS >8 before intubation and DIII or DIV. CT brain scan basal cistern compression ± midline shift
4. Intracanial pressure (ICP) monitor in situ
5. 'Refractory ICP' despite best conventional management. Refractory ICP in this study will be defined as the spontaneous persistent increase in ICP despite optimal conventional ICU therapies (including intermittent external ventricular drain [EVD] venting) of >20 mm Hg for more than 15 mins (continuously or cumulative over one hour).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Intracranial mass lesion (>3 cm diameter) and/or previous craniectomy
2. Extradural hematoma / subdural hematoma (EDH/SDH) requiring evacuation
3. EDH/SDH >0.5 cm thickness
4. Spinal cord injury
5. Penetrating brain injury
6. Arrest at scene
7. Unreactive pupils >4 mm and GCS = 3
8. Neurosurgery contraindicated
9. No chance of survival after consideration of CT and clinical findings, following Neurosurgical consultant assessment

Date of first enrolment
01/08/2003

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
Australia

Study participating centre
The Alfred Hospital
Melbourne
Australia
3004

Sponsor information

Organisation
National Trauma Research Institute, The Alfred Hospital (Australia)

ROR
https://ror.org/01wddqe20

Funder(s)

Funder type
Research council

Funder Name
Australian and New Zealand Intensive Care (ANZIC) Foundation (Australia/New Zealand)

Funder Name
Victorian Trauma Foundation (Australia)

Funder Name
Western Australian Institute for Medical Research (WAIMR), Neurotrauma Research Programme (Australia)

Funder Name
National Health and Medical Research Council (ref: 314502)

Alternative Name(s)
National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2008		Yes	No
Results article	results	21/04/2011		Yes	No