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Decompressive craniectomy for mass effect in severe head injury

Submission date	Recruitment status	[X] Prospectively registered
14/05/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/05/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/01/2016	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Severe traumatic brain injury (STBI) occurs when external force greatly injures the brain. When leaking blood or swelling compresses the surrounding areas of the brain, it can be life threatening. This can be treated with an emergency operation in which a section of the skull, called a bone flap, is removed to access the brain underneath. The bone flap is then either put back (craniotomy, CO) or removed (decompressive craniectomy, DC). CO ensures that the skull is intact but there is a risk of brain compression later. DC expands the limited skull space but is associated with many complications, and also requires a second operation to repair the skull defect (cranioplasty). There are currently two treatment methods. One is primary DC (prophylactic DC). The other is primary CO unless DC is necessary to reduce the brain pressure (therapeutic DC). The aim of this study is to confirm which is the better treatment for STBI patients.

Who can participate?
STBI patients aged between 15 and 65.

What does the study involve?
Participants will be randomly allocated to be treated with either prophylactic DC or therapeutic DC. Participants will be followed up with brief questionnaire at 1 month, 6 months and 12 months after surgery.

What are the possible benefits and risks of participating?
Participants may not directly benefit from the study, but the study will provide useful information for surgeons when they explain the treatment choices to patients. We have considered the potential risks in either group and also have made a detailed emergency plan for participants.

Where is the study run from?
West China Hospital of Sichuan University (China).

When is the study starting and how long is it expected to run for?
The study will start in June 2015 and will run until June 2020.

Who is funding the study?
West China Hospital of Sichuan University (China).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Prospective Randomized Evaluation of therapeutic decompressive Craniectomy In Severe traumatic brain injury with mass lesions (PRECIS)

Acronym
PRECIS

Study objectives

Does therapeutic decompressive craniectomy which is intervened based on the emergence of intraoperative brain swelling, lead to a better outcome compared to prophylactic decompressive craniectomy in primary operation for severe traumatic brain injury patients with mass lesions?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Clinical Trials and Biomedical, West China Hospital, Sichuan University, first edition approval date 24/04/2015, approval number 2015 (17)

Study design
Prospective randomized assessor-blind single-center clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Once the eligible patient signs consent and confirms randomization, the interventions commence. Participants will be randomly allocated to either prophylactic DC group or therapeutic DC group. During operation preparation, the best medical treatments will be administrated to all patients following the recommendations of The Brain Trauma Foundation guidelines. Intraparenchymal or intraventricular ICP monitor should be placed in the lesion side before craniotomy and kept at least for 5 days after surgery.
The unilateral trauma craniotomy model is preferred. The range of craniotomy will reach at least 15×12cm, extend down to the temporal base and curve around the parietal lobe to the side within 2cm of mid-line. After mass evacuation, the dura will be sutured on relaxation and expansion by the temporal fascia or artificial dura. Then for the prophylactic DC group, the bone flap will be removed. And for the therapeutic DC group, the only criterion for the bone flap reposition whether or not is the emergence of intraoperative brain swelling.
Treatment target is maintaining ICP < 20 mmHg and CPP > 60 mmHg. The postoperative stepwise therapies will be provided in NICU. First-tier therapies include sedation, neuromuscular blockade, intubation, ventilation, 30° head elevation, osmotic dehydration and external ventricular drainage. Second-tier therapy is hypothermia (32°–34°). For the craniotomy patients in therapeutic DC group, salvage DC will be used subsequently if the ICP is continually > 25 mmHg for 1 h without downtrend even after all other treatments had been attempted.

Cranioplasty will be recommended within 3–6 months for all the DC patients.
Scheduled CT scan will be performed at 1 day, 3 days, 7 days and 30 days after surgery.
Responsible physicians may plan the unscheduled CT scan in accordance with specific conditions.

Intervention Type
Procedure/Surgery

Primary outcome measure
Favorable outcome at 12 months after randomization, measured by Extended Glasgow outcome scale (5–8)

Secondary outcome measures
1. Quality of life (EQ-5D) at 6 and 12 months after randomization
2. Mortality at 6 months and 12 months after randomization
3. Incidence of re-operation with salvage DC in craniotomy patients of therapeutic DC group at one month after randomization
4. ICP and CPP control during 1 week after randomization (intraoperative and postoperative)
5. Complications at 1 month, 6 months and 12 months

Overall study start date
01/06/2015

Completion date
01/06/2020

Eligibility

Key inclusion criteria
1. Age between 15 and 65 years old
2. Glasgow Coma Scale (GCS) ≤ 8
3. Marshall Classification VI, presence of high- or mix-density lesion ≥ 25 ml (contusion, intraparenchymal and subdural hematoma)
4. Neurological status progressive deterioration within 24 h after injury (GCS motor score fall by 2 points or blunt pupillary response)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
336 (plus safe margin of 10% loss to follow-up)

Key exclusion criteria
1. Bilateral mydriasis of critically endangered status
2. Cerebellum contusion

3. Penetrating brain injury
4. Serious extracranial injury with unstable vital signs
5. Beyond 24 h after injury
6. Known cognitive or neurological impairment
7. Breastfeeding or pregnancy
8. Definite surgical contraindications

Date of first enrolment
08/06/2015

Date of final enrolment
08/06/2019

Locations

Countries of recruitment
China

Study participating centre
West China Hospital
No. 37 Guoxue Xiang
Chengdu
China
610041

Sponsor information

Organisation
West China Hospital of Sichuan University (P. R. China)

Sponsor details
No. 37 Guoxue Xiang
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China
610041

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/007mrxy13

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
West China Hospital of Sichuan University (P. R. China)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/01/2016		Yes	No