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# Study of the effectiveness of craniotomy on patients with acute post-traumatic brain swelling after severe traumatic brain injury

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 10/02/2009 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 03/04/2009 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 04/05/2010 | Injury, Occupational Diseases, Poisoning | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

2008R40G2150132

# Study information

### Scientific Title
Study of the effectiveness of craniotomy (Decompressive Craniectomy [DC] or routine temporoparietal craniectomy) on patients with Acute post-traumatic Brain Swelling after severe traumatic brain injury: a single-centre, prospective randomised, controlled, double-blind trial

### Acronym
DCABS

### Study objectives
The aim of the present clinical study was to assess the efficacy of craniotomy, decompressive craniectomy (DC) or routine temporoparietal craniectomy, on patients with acute post-traumatic brain swelling (BS). We assume that DC has superior effectiveness on patients with acute BS after severe traumatic brain injury.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Institutional Review Board and the ethical committees of Clinical Medical College of Hangzhou gave approval on the 1st September 2002 (ref: 200203)

### Study design
Single-centre prospective randomised controlled double-blind trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Acute post-traumatic brain swelling

### Interventions
Based on the guidelines for the management of severe head injury set forth by the Joint Section on Neurotrauma and Critical Care of the Brain Trauma Foundation and the American Association

of Neurological Surgeons, all patients underwent lateral craniotomy within 24 hours after injury and other medical management such as dehydration with mannitol (average amount received in subsequent 6-hour period was 20% mannitol 125 ml) and routine pharmacological or physical measures adopted to maintain normal body temperature after diagnosis of post-traumatic BS accordingly.

The surgery mode of DC was elective at the frontoparietotemporal region, based on the lesion location and midline shift determined by CT scans. Briefly, the bone window was about 15 cm in diameter with duraplasty using expanded dura substitute when necessary. The anterior was frontal to the midpupillary lines, and the posterior line was about 3 - 4 cm posterior to the external acustic meatus. The superior line was 2 cm of the lateral edge of the superior sagittal sinus, and the inferior line was extended below the level of the zygomatic arch, so that the frontal and temporal base could be explored. Durotomy was performed over the entire region of bony decompression as a stellate shape. Cranioplasty was performed after 3 months.

Post-operative therapy was similar with those previously described, which included keeping respiratory tract unobstructed (with assisted ventilation to ensure arterial O2 saturation (SaO2) greater than or equal to 95% against hypoxia and partial pressure of carbon dioxide in arterial blood (PaCO2) maintained near 40mm Hg at 37°C), intubations if necessary, controlling the blood glucose level and body temperature and balancing water and electrolyte, dehydration and diuresis, homeostasis balanced, anti-infection with sensitive antibiotics and so on.

The control group received the unilateral routine temporoparietal craniectomy and the operation site depended on the location of injury and midline shift accordingly. The bone window diametered about 8 cm and the dura mater was also fixed at the edge with duraplasty, and the bone was re-implanted after 3 - 6 months. In the routine craniotomy group, post-operative treatment was similar with those in the DC group.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
1. Intracranial pressure (ICP) - continuous recording of ICP was applied in all patients for 96 hours with the ICP monitor system (Camino-MPM1, Integra LifeSciences CO, USA). A cranial hole was drilled, if necessary, and the drainage catheter was induced 5 cm or so into right lateral ventricles via the level of the anterior horn. The intraventricular (intracerebral) pressure probe (Camino-110-4B) was placed at the level of foramen of Momro during craniotomy.
2. Glasgow Outcome Scale (GOS) scores, from 1 to 5 respectively, according to: death, vegetable state, severe disability, moderate disability, mild or no disability, evaluated at 1 years follow-up after injury

### Secondary outcome measures
1. Vital signs (temperature, heart rate, breathing rate and blood pressure), arterial oxygen saturation with the multiple monitor (Model NO: 90309, Space Lab, Medical. Inc. USA) recorded every 12 hours for 7 days after craniotomy
2. Complications, mainly inclusive of delayed intracranial haematoma, pulmonary infection,

digestive tract haemorrhage, and electrolytes disorders (beyond the normal serum concentrations of Na+, Cl-, Mg2+, K+, P3+ and Ca2+), recorded every 12 hours for 7 days, 24 hours for another 7 days after craniotomy

### Overall study start date
01/01/2003

### Completion date
01/12/2008

## Eligibility

### Key inclusion criteria
1. Aged from 18 to 65 years, either sex
2. A history of traumatic brain injury
3. Glasgow Coma Score (GCS) less than or equal to 8 at admission
4. Computed tomography (CT) scans: swollen hemisphere (with midline shift greater than 5 mm, compressed basal cisterns) within 24 hours after trauma

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
80

### Key exclusion criteria
1. Patients younger than 19 or older than 65 years
2. Multiply-injured patients without sufficient resuscitation
3. With any previous disabling neurological disease
4. Intracerebral haematoma of more than 3 cm in diameter
5. Spinal cord injury
6. Penetrating brain injury
7. Fixed dilated pupils and GCS score of 3 with no chance of survival

### Date of first enrolment
01/01/2003

### Date of final enrolment
01/12/2008

## Locations

### Countries of recruitment
China

### Study participating centre
**126 Wengzhou Road**
Hangzhou
China
310015

## Sponsor information

### Organisation
Zhejiang and Hangzhou Health Department (China)

### Sponsor details
2 Xiaonv Road
Hangzhou
China
310009

### Sponsor type
Government

## Funder(s)

### Funder type
Government

### Funder Name
Zhejiang and Hangzhou Health Department (China) - Scientific Research Fund (ref: 2009)

## 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 | 01/11/2009 | | Yes | No |