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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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
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310015

Sponsor information

Organisation
Zhejiang and Hangzhou Health Department (China)

Funder(s)

Funder type
Government

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

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes