

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

Submission date
10/02/2009

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
03/04/2009

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
04/05/2010

Condition category
Injury, Occupational Diseases, Poisoning

☐ Individual participant data

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)

Primary study design

Interventional

Study design

Single-centre prospective randomised controlled double-blind trial

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 acoustic 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 Monro 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

Hangzhou

China

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