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Application of Multiple Cerebral Monitoring Severe Traumatic Brain Injury: a multicentre study

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31/08/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/07/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/10/2021	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Wen-Ta Chiu

Contact details
No. 250 Wu-Hsing Street
Taipei
Taiwan
111
+886 (0)2 2739 0217
wtchiu@tmu.edu.tw

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Application of Multiple Cerebral Monitoring Severe Traumatic Brain Injury: a multicentre study

Acronym
AMCMSTBI

Study objectives
Significant reduction in mortality and morbidity can be achieved by using intensive management protocols. Compared to early studies of 50% mortality, the results of efforts in investigating the proper procedures among each stages, reveals a reduction of mortality rate to average of 36% among severe head injured patients. Kiening et al. reported that the elevation of the Cerebral Perfusion Pressure (CPP) from 32 to 67 mmHg improved cerebral tissue oxygenation (PtO2) by 62%. Recent studies also showed that the mortality significantly decreased in the group of PtO2 of monitoring. However, there are still debates about the optimal CPP, especially in the patient with impaired pressure autoregulation. Nevertheless, optimal Inter-Cranial Pressure (ICP) and CPP management may not always prevent cerebral ischaemia, which adversely influences patient outcome.

The aims of this study are:
1. To evaluate the efficacy of multiple cerebral monitoring
2. To find the optimal CPP in different groups with autoregulation in the treatment of Severe Traumatic Brain Injury (STBI)
3. To investigate the outcome difference (Glasgow Outcome Score [GOS], Glasgow Outcome Score Extended [GOSE], survival analysis and Health-related Quality Of Life [HQOL]) among patients with different monitoring groups

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval gained from the local ethics committee on the 1st June 2006 (reference number: F950402).

Study design
Interventional, prospective, multicentred, randomised controlled study.

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

Interventions
The hospitals included in this series were Wan Fang Hospital, Veterans General Hospital, Taipei, National Taiwan University Hospital, Mackay Memorial Hospital, Shin Kong Wu Ho-Su Memorial Hospital and Taipei Tri-Service General Hospital. Twenty to thirty patients are provided from each medical centre.

All the subjects are randomised (block in four) and divided in to the study group (Group A) or control group (Group B):
Group A: multiple cerebral monitoring systems, ICP, PtO2 and the TransCranial Doppler (TCD74)
Group B: ICP monitoring only
The major differences between the Group A and Group B are the treatment goals. In the Group A, PtO2 of at least 25 - 30 mmHg is maintained, by the adjustment of CPP. In Group B, Mean Arterial Pressure (MAP) was kept at 90 mmHg or more and CPP was maintained at a minimum of 60 - 70 mmHg.

Cerebral monitoring:
1. The TransCranial Doppler (TCD) insonation was performed using a 2 MHz real time and pulse-Doppler transducer. For continuous monitoring, the 2 MHz probe was applied at a temporal window with a fixed head holder (Spenser Marco 600) connected to the TCD monitor (Nicolet /EME Companion II, Germany) to detect the Middle Cerebral Artery (MCA) at the depth of 55 - 65 cm and to record the Mean Flow Velocity (MFV)
2. An intraparenchymal ICP monitor (Codman electrode MicroSensor, Johnson & Johnson Medical, Ltd., USA) was used for monitoring the ICP. The ICP monitor was connected to a Hewlett Packard (HP) monitor, model 66s-M116A, via a pressure transducer (Codman neuromonitor interface control unit, 82-6605) and module
3. An intraparenchymal brain tissue combined Oxygen and Temperature probe (LICOX REFIT2, Integra NeuroSciences, Ltd., England) was used for monitoring the PtO2. The PtO2 probe monitor is placed in the healthy side of brain parenchyma. The signals are transmitted to a HP monitor, via a transducer box (LICOX REF POM.BOX, Integra NeuroSciences, Ltd., England) and monitor cable (LICOX REF NL950-MC-01, Integra NeuroSciences, Ltd., England)

Standard management:
In the intensive care unit, patients were positioned in bed with an approximately 30° head up. Monitoring involved in simultaneous and continuous assessment of MAP from a radial or brachial arterial line, electrocardiogram, pulse oximetry values, and End-tidal Carbon Dioxide (EtCO2) by capnography. Central venous pressure and body temperature were assessed either continuously or intermittently at frequent intervals. Routine pharmacological or physical measures were adopted to avoid fever if body temperature levels were 37.5°C or higher. Mechanical ventilation was adjusted to keep EtCO2 between 30 and 33 mmHg. Sedation with propofol titration is used for ICP control. Patients underwent complete neurological assessment by nursing staff hourly or more frequently if the condition was deteriorating.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
1. Application of multiple cerebral blood monitor in the treatment of STBI could result in reduced mortality rate and impaired quality of life
2. Patients with impaired autoregulation, the optimal CPP value could be changed

Secondary outcome measures
1.Through this study, the result could be contributed to the establishment of a new Clinical Practice Guideline of STBI
2. The result could be used as a guideline to train young physicians
3. In different groups, patients with multiple cerebral monitoring will have better GOS, GOSE, HRQL, and survival

Overall study start date
01/09/2006

Completion date
31/12/2011

Eligibility

Key inclusion criteria
Glasgow Coma Scale (GCS) score three to eight will be enrolled in this study.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
320

Key exclusion criteria
1. Patients manifesting severe systemic injury with hypotension (systolic blood pressure less than 90 mmHg on admission)
2. GCS score three with fixed and dilated pupils after resuscitation
3. GCS score three to four with family refused aggressive treatment
4. Patients transferred from another institution longer than 24 hours after injury
5. Those who were dead on arrival

Date of first enrolment
01/09/2006

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Taiwan

Study participating centre
No. 250 Wu-Hsing Street
Taipei
Taiwan
111

Sponsor information

Organisation
Department of Health, Taipei City Government (Taiwan)

Sponsor details
1, No.1, Shifu Road
Xinyi District
Taipei
Taiwan
110
+886 (0)2 2728 7070
yuhhuey@health.gov.tw

Sponsor type
Government

Website
http://english.taipei.gov.tw/health/index.jsp

ROR
https://ror.org/02eqw3q87

Funder(s)

Funder type
Government

Funder Name
Department of Health, Taipei City Government (Taiwan)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration