Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Controlled decompression effects in the patients with severe TBI: A Randomized Control Trial

Protocol summary

Study aim
To investigate whether controlled decompression therapy reduces the incidence of comorbidities and enhances recovery in traumatic brain injury patients

Design
A two arm parallel group randomised trial with blinded postoperative care and outcome assessment on a total sample of 52 participants.

Settings and conduct
The study was conducted at the neurosurgery unit, Afridi Medical Complex. Patients with elevated ICP underwent therapeutic hypothermia for 7–10 days. ICP was regularly checked with an ICP sensor, which was normally taken out around a week following surgery. Every two hours, the ICP and vital signs were monitored and noted. If the patients were stable at 1, 24, and 72 hours following the procedure, the cranial CT data were routinely evaluated. The outcome assessor during the process will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with TBI between the ages of 18 and 75 who gave informed permission and had a Glasgow Coma Scale (GCS) score between 3 and 8 at admission were eligible. Exclusion criteria: Exclusion criteria included the following: initial need for bilateral craniotomy; preoperative GCS score of 3 with no improvement after treatment in the emergency room; presentation without attenuated respiration

Intervention groups
Experimental group: Standard surgical techniques were used to achieve a rapid craniotomy. The fast removal of the hematoma and brain contusion tissue was the main objective of the procedure. Control Group: The best option was a brain tissue monitor, followed by a ventricular intracranial pressure monitor. The dura was completely opened, and the hematoma or brain contusion tissue was then removed when the ICP was less than 10 mmHg and there were no visible evidence of bulging brain tissue.

Main outcome variables
The Extended Glasgow Outcome Scale (GOSE)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230907059376N1**
Registration date: **2023-09-13, 1402/06/22**
Registration timing: **retrospective**

Last update: **2023-09-13, 1402/06/22**
Update count: **0**

Registration date
2023-09-13, 1402/06/22

Registrant information

Name
Sarmad Khattak

Name of organization / entity
Rehman Medical Institute, Peshawar

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-13, 1401/05/22

Expected recruitment end date
2023-08-13, 1402/05/22

Actual recruitment start date
2022-09-21, 1401/06/30

Actual recruitment end date
2023-08-13, 1402/05/22

Trial completion date
2023-08-27, 1402/06/05

Scientific title
Controlled decompression effects in the patients with severe TBI: A Randomized Control Trial

Public title
Controlled decompression effects in the patients with severe TBI: A Randomized Control Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with TBI between the ages of 18 and 75 Patients who gave informed permission Glasgow Coma Scale (GCS) score between 3 and 8 at admission

Exclusion criteria:
Initial need for bilateral craniotomy Preoperative GCS score of 3 with no improvement after treatment in the emergency room Presentation without attenuated respiration and blood pressure Combination of anoxia and hypotension with brain swelling caused by anoxia or hypotension and minor intracranial bleeding after injury Coagulation disorder or a history of aspirin intake and multiorgan malfunction

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **52**
Actual sample size reached: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
In our trial, randomization was conducted using a computer-generated random sequence that allocated participants into one of two groups: controlled decompression or fast decompression, following Traumatic Brain Injury (TBI) prior to surgery. This randomization process ensured that each participant had an equal and unbiased chance of being assigned to either group, minimizing potential selection bias and allowing for a more reliable assessment of the treatment outcomes.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Afridi Medical Complex ethical committee

Street address
Afridi medical complex tehkal payan, University Rd, Tehkal, Peshawar, Khyber Pakhtunkhwa

City
Peshawar

Postal code
25150

Approval date
2022-07-13, 1401/04/22

Ethics committee reference number
AMI/NS/10

Health conditions studied

1

Description of health condition studied
Traumatic brain injury

ICD-10 code
S06.2

ICD-10 code description
Diffuse traumatic brain injury

Primary outcomes

1

Description
Global disability and recovery after traumatic brain injury

Timepoint
Baseline and after 6 months

Method of measurement
Extended Glasgow Outcome Scale (GOSE)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Standard surgical techniques were used to achieve a rapid craniotomy.The dura was entirely opened by a normal large craniotomy (12 to 15 cm), allowing the ICP to be quickly, totally, and uncontrollably discharged. ICP monitoring was given to each patient in this group. The intraoperative surgical approach did not take the ICP into account, and the rate of ICP decline was not managed during the procedure. The fast removal of the hematoma and brain contusion tissue was the main objective of the procedure.

Category
Treatment - Surgery

2

Description
Control group: The goal of controlled decompression was to guarantee that the ICP would gradually release over the whole treatment using a variety of techniques. ICP dropped at a rate of 10-15 mmHg per 10 minutes. Before the craniotomy, an ICP probe was implanted to get the initial ICP. The best option was a brain tissue monitor, followed by a ventricular intracranial pressure monitor. Cerebrospinal fluid (CSF) was gradually discharged until the ICP was > 40 mmHg if the initial ICP was greater than that value. Second, to pressurize the brain and prevent a sharp drop in ICP after the bone was removed, a craniotomy with a bone window (12 ×15 cm) was necessary. Third, a small incision no bigger than 5 mm, which is frequently the diameter of the aspirator head, was used to breach the dura. The ICP was steadily decreased while the hematoma and brain contusion tissue were carefully aspirated. The dura was completely opened, and the hematoma or brain contusion tissue was then removed when the ICP was less than 10 mmHg and there were no visible evidence of bulging brain tissue.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Afridi Medical Complex, Peshawar

Full name of responsible person
Mehboob Khan

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Afridi Medical Complex, Peshawar

Proportion provided by this source
50

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Royal Preston Hospital, Preston UK

Full name of responsible person
Abdul Hameed Khan

Position
Junior Clinical Fellow

Latest degree
Medical doctor

Other areas of specialty/work
Neurosurgery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Controlled decompression effects in the patients with severe TBI: A Randomised Control Trial
When the data will become available and for how long
Next year
To whom data/document is available
Neuro surgeon
Under which criteria data/document could be used
Through email
From where data/document is obtainable
Contacting Principal author through email
What processes are involved for a request to access data/document
Contact Principal author Dr Mhaboob through email. Email of the author is: mehbob509@gmail.com
Comments