

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 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

Country

Pakistan

Phone

+92 91 5838666

Email address

sarmadkhattak007@gmail.com

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 x15 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

Street address

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

City

Peshawar

Postal code

25150

Phone

+92 91 5711751

Email

mehbob509@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Afridi Medical Complex, Peshawar

Full name of responsible person

Mahboob Khan

Street address

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

City

Peshawar

Postal code

25150

Phone

+92 91 5711751

Email

mehboob509@gmail.com

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

Street address

Sharoe Green Ln, Fulwood, Preston PR2 9HT, UK

City

Preston

Province

Preston

Postal code

PR2 9HT

Phone

+44 1772 716565

Email

drhameedkhan@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Afridi Medical Complex, Peshawar

Full name of responsible person

Mahboob Khan

Position

Consultant Neurosurgeon

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

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

City

Peshawar

Province

Khyber Pakhtunkhwa

Postal code

25150

Phone

+92 91 5711751

Email

mehboob509@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Afridi Medical Complex, Peshawar

Full name of responsible person

Mahboob Khan

Position

Consultant Neurosurgeon

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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

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Peshawar

Province

Khyber Pakhtunkhwa

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25150

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Email

mehboob509@gmail.com

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