

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Intracranial Pressure Monitoring on Clinical Outcome and Mortality in Patients With Severe Traumatic Brain Injury

Protocol summary

Study aim

Effect of Intracranial Pressure Monitoring on Clinical Outcome and Mortality in Patients With Severe Traumatic Brain Injury

Design

The study will be double blind and clinical trial. 120 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Patients With Severe Traumatic Brain Injury in Valiasr Hospital in Arak are divided into 2 groups by simple randomization with blocks. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/inclusion and exclusion criteria

Inclusion criteria: Patients with head trauma, systolic pressure above 90 mm Hg, 18 years and above
Exclusion criteria: Death in the first 48 hours, mydriatic pupils are bilateral, Dissatisfaction

Intervention groups

Intervention group: The ICP monitoring device will be used for the participants in the intervention group. Patients will undergo intracranial pressure monitoring surgery within 6 hours of admission. Control group: routine treatment measures are performed based on the guideline "Dealing with severe head trauma patients 2007".

Main outcome variables

Glasgow Outcome Scale, mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N180**

Registration date: **2023-01-01, 1401/10/11**

Registration timing: **prospective**

Last update: **2023-01-01, 1401/10/11**

Update count: **0**

Registration date

2023-01-01, 1401/10/11

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Intracranial Pressure Monitoring on Clinical Outcome and Mortality in Patients With Severe Traumatic Brain Injury

Public title

Effect of Intracranial Pressure Monitoring on Clinical Outcome and Mortality in Patients With Severe Traumatic Brain Injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with head trauma Systolic pressure above 90 mm Hg 18 years and above

Exclusion criteria:
Death in the first 48 hours Mydriaz winx pupils are bilateral Dissatisfaction

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

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

Ethics Committe Arak University Of Medical Sciences

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

848176941

Approval date

2021-12-26, 1400/10/05

Ethics committee reference number

IR.ARAKMU.REC.1400.282

Health conditions studied

1

Description of health condition studied

Severe Traumatic Brain Injury

ICD-10 code

S06.1X7

ICD-10 code description

Traumatic cerebral edema with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness

Primary outcomes

1

Description

Glasgow Outcome Scale

Timepoint

Afetr intervention

Method of measurement

Glasgow Questionnaire

2

Description

Mortality

Timepoint

Afetr intervention

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The ICP monitoring device will be used for the participants in the intervention group. Patients will undergo intracranial pressure monitoring surgery within 6 hours of admission.

Category

Treatment - Surgery

2

Description

Control group: routine treatment measures are performed based on the guideline "Dealing with severe head trauma patients 2007".

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Alireza Mohammadi

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3417 3645

Fax

+98 86 3222 2003

Email

nazemi@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mahdi Salehi

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

solhi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Mohammadi

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Shahid Shirodi street, Valiasr square, Valiasr hospital, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

mohamadi@arakmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Mohammadi

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

mohamadi@arakmu.ac.ir

Web page address

Person responsible for updating data

amini@gmail.com

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Hamed Vahdani

Position

resident of neurosurgery

Latest degree

Specialist

Other areas of specialty/work

General Practitioner

Street address

Payambar Azam Complex, Basij square, Sardasht,
Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available