

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of effect of intracranial pressure monitoring catheter employment on prognosis of severe head trauma patient in Al Zahra hospital

Protocol summary

Study aim

Determining the effect of intracranial pressure monitoring catheter employment on prognosis of severe head trauma patient in Al Zahra hospital

Design

Participants in the study were randomly divided into two groups of clinical examination and CT scan (control group) and catheter (intervention group) based on the case records. The sample size was considered as 10 in each group.

Settings and conduct

In the ICU, ICP will be continuously monitored and, if pressure is higher than 22 mmHg, treatment will be start in accordance with the fourth edition of the Guide for the treatment of severe brain injury. Patients in this group will be screened for surgical site infection and meningitis (in case of clinical symptoms). In the control group, a clinical examination and CT scan will be performed at specific intervals and, in the case of a change in the clinical or radiological status of patients, appropriate treatment will be taken based on the fourth edition of the Guide for the treatment of severe brain injury.

Participants/Inclusion and exclusion criteria

Among all patients referred to our trauma center those who met the criteria for ICP monitoring according to the Guidelines for the Management of Severe Traumatic Brain Injury (4th edition), were enrolled.

Intervention groups

Intervention group: After transferring the patient into the operating room and under general anesthesia, the Spiegelberg Probe 3PN catheter will enter the brain through a hole in the frontal region of skull. Control group: Patients with severe brain trauma undergoing periodic clinical examination and control CT scans.

Main outcome variables

Glasgow outcome scale extended

General information

Reason for update

Acronym

ICPmo

IRCT registration information

IRCT registration number: **IRCT20180813040788N1**

Registration date: **2019-08-29, 1398/06/07**

Registration timing: **retrospective**

Last update: **2019-08-29, 1398/06/07**

Update count: **0**

Registration date

2019-08-29, 1398/06/07

Registrant information

Name

Saeed Sattaei Mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

saeedmokhtari367@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

2018-10-23, 1397/08/01

Actual recruitment end date

2018-12-21, 1397/09/30

Trial completion date

2019-01-05, 1397/10/15

Scientific title

Evaluation of effect of intracranial pressure monitoring catheter employment on prognosis of severe head trauma patient in Al Zahra hospital

Public title

ICP Monitoring

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with consciousness levels of 3 to 8 (based on GCS criteria) and abnormal brain CT scans (including bleeding, cantogens, edema, brain hernia symptoms, or compression of brain cytars) that can be rescued, and patients with a level of consciousness 3 to 8 (based on GCS criteria) and normal brain CT scan older than 40 years of age, systolic blood pressure less than 90 mm Hg, or abnormal motor status in a clinical examination.

Exclusion criteria:

Patients who are reluctant to continue studying are excluded.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

the patients were randomly allocated with proper statistics soft wares into two groups on patients.

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 Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib Avenue Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2017-12-23, 1396/10/02

Ethics committee reference number

IR.mui.med.REC.1397.036

Health conditions studied

1

Description of health condition studied

Intracranial injury

ICD-10 code

S06.0

ICD-10 code description

Concussion

2

Description of health condition studied

Intracranial injury

ICD-10 code

S06.1

ICD-10 code description

Traumatic cerebral edema

3

Description of health condition studied

Intracranial injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

4

Description of health condition studied

Intracranial injury

ICD-10 code

S06.3

ICD-10 code description

Focal traumatic brain injury

5

Description of health condition studied

Intracranial injury

ICD-10 code

S06.4

ICD-10 code description

Epidural hemorrhage

6

Description of health condition studied

Intracranial injury
ICD-10 code
S06.5
ICD-10 code description
Traumatic subdural hemorrhage

7

Description of health condition studied
Intracranial injury
ICD-10 code
S06.6
ICD-10 code description
Traumatic subarachnoid hemorrhage

8

Description of health condition studied
Intracranial injury
ICD-10 code
S06.8
ICD-10 code description
Other specified intracranial injuries

9

Description of health condition studied
Intracranial injury
ICD-10 code
S06.9
ICD-10 code description
Unspecified intracranial injury

Primary outcomes

1

Description
Prognosis of patients with severe brain trauma
Timepoint
Determination of prognosis of patients with severe traumatic brain injury on discharge
Method of measurement
The Glasgow Outcome Scale Extended (GOS-E)

Secondary outcomes

1

Description
Surgical site infection
Timepoint
During the hospitalization
Method of measurement
Clinical signs and symptoms and Cultivation of the wound site

2

Description
Meningitis
Timepoint

During the hospitalization
Method of measurement
Clinical signs and symptoms and cerebrospinal fluid culture

Intervention groups

1

Description
Intervention group: Patients in this group will receive intracranial pressure monitoring catheter (Spiegelberg probe 3PN) and intracranial pressure lowering treatments will be performed based on intracranial pressure value according to the study protocol.
Category
Early detection

2

Description
Control group: In these patients intracranial pressure lowering treatments will be performed according to neurological examination and serial imaging according to the study protocol.
Category
Early detection

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Medical Center
Full name of responsible person
Saeed Sattaiei Mokhtari
Street address
Safeh Boulevard, Al-Zahra Medical Center
City
Isfahan
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Postal code
8174675731
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Email
saeedmokhtari367@gmail.com
Web page address
<http://alzahra.mui.ac.ir/>

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Saeed Sattaiei Mokhtari
Street address

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Email

saeedmokhtari367@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Saeed Sattaei Mokhtari

Position

Resident of neurosurgery

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Saeed Sattaei Mokhtari

Position

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Latest degree

Medical doctor

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Person responsible for updating data

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Latest degree

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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
Data could be shared after Unidentifiable people.
When the data will become available and for how long
6 months after publishing results
To whom data/document is available
Researchers working in academia

Under which criteria data/document could be used
Via email at saeedmokhtari367@gmail.com
From where data/document is obtainable
Via email at saeedmokhtari367@gmail.com
What processes are involved for a request to access data/document
After confirmation by the scientific team
Comments