

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigation and comparison of intravenous infusion of sodium pentotal on the neurological outcomes of patients undergoing decompressive craniectomy with intra-operative brain swelling in Ahvaz Golestan hospital in 2020

Protocol summary

Study aim

Investigation and comparison of intravenous infusion of sodium pentotal on the neurological outcomes of patients undergoing decompressive craniectomy with intra-operative brain swelling in Ahvaz Golestan hospital in 2020

Design

Clinical trial with control group, double-blind and randomized, phase 3 In 48 patients

Settings and conduct

Patients undergoing decompression craniotomy in the neurosurgery ward of Ahvaz Golestan Hospital in 2020. The patients, the intervener, and the person reviewing the results did not know what group the individuals were in, and the study would be conducted in a two double-blind,

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing decompression craniotomy due to increased intracranial pressure with various causes that have brain edema during brain surgery despite the removal of the skull. Inclusion criteria: Age less than 12 years and more than 60 years - Patient or guardian's dissatisfaction to participate in the study - Patients with known psychiatric history - Patients with underlying degenerative brain disease - No brain swelling during surgery - Pregnant patients - Patients with Glasgow Coma Score 3

Intervention groups

Intervention group: They are treated with intravenous injection of sodium thiopental for 48 hours after surgery and a barbiturate coma is induced in them. Control group: Patients were treated with injected distilled water according to the conditions of the intervention group.

Main outcome variables

Evaluation of Glasgow coma score and Glasgow outcome score in 2 weeks, 1 month and 3 months after

decompressive craniotomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200817048436N1**

Registration date: **2020-11-04, 1399/08/14**

Registration timing: **retrospective**

Last update: **2020-11-04, 1399/08/14**

Update count: **0**

Registration date

2020-11-04, 1399/08/14

Registrant information

Name

yousef seydi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3250

Email address

seidi19850@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-10, 1399/02/21

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

2020-05-10, 1399/02/21

Actual recruitment end date

2020-09-20, 1399/06/30

Trial completion date

2020-09-20, 1399/06/30

Scientific title

Investigation and comparison of intravenous infusion of sodium pentotal on the neurological outcomes of patients undergoing decompressive craniectomy with intra-operative brain swelling in Ahvaz Golestan hospital in 2020

Public title

Investigation and comparison of intravenous infusion of sodium pentotal on the neurological outcomes of patients undergoing decompressive craniectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with increased ICP that undergo decompressive craniotomy

Exclusion criteria:

Age less than 12 years and over 65 years
Dissatisfaction of the patient or his guardian to participate in the study
Patients with a known psychiatric history
Patients with degenerative underlying brain disease
No swelling of the brain during surgery
Pregnant mothers
Patients with Glasgow Coma Scale/Score: 3 at baseline
Patients with Glasgow Coma Scale/Score: 4 and bilateral pupillary mydriasis at baseline

Age

From **12 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided into two groups A and B. Block randomization methods were used. The size of the block was four and in each block 2 patient in group A and 2 patient in group B were assigned. The order of groups A and B within each block was determined randomly using function (RAND) in Excel software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the interventionist and the person examining the results did not know what group the individuals were in, and the study would be double blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences (AJUMS)

Street address

Khuzestan Province, Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

۵۶۱۸۹-۸۵۹۹۱

Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.AJUMS.REC.1399.147

Health conditions studied**1****Description of health condition studied**

Craniocerebral Trauma

ICD-10 code

S06.1X7A

ICD-10 code description

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

Primary outcomes**1****Description**

Glasgow Coma Scale

Timepoint

From the moment of starting treatment until the time of hospitalization and also during 1 and 3 months after that

Method of measurement

Scoring between 3 and 15

2**Description**

Glasgow Outcome Scale

Timepoint

From the moment of starting treatment until the time of hospitalization and also during 1 and 3 months after that

Method of measurement

Clinical examination of the patient

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the intervention group, patients received continuous thiopental infusion (Ciron company) at a dose of 2 mg / kg / h as barbiturate coma therapy (BCT) for 2 hours after surgery.

Category

Treatment - Drugs

2**Description**

Control group: Patients received distilled water for injection with the same conditions as the intervention group

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Neurology Department of Golestan Hospital, Ahvaz

Full name of responsible person

Dr. Yousef Seidi

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Ahvaz, Farvardin Blvd., Golestan hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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Grant name

Ahvaz Jundishapur University of Medical Sciences

Grant code / Reference number

U-99065

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

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Yousef Seidi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Latest degree

Medical doctor

Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available