Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

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+98 61 3374 3250

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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 Ahwaz Jundishapur University of Medical Sciences (AJUMS)
Street address
Khuzestan Province, Ahvaz
City
Ahvaz
Province
Khouzestan
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
Glascow 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 asbarbiturate 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
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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
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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