

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of mannitol and hypertonic sodium administration to reduce ICP on hemodynamic parameters under LiDCO monitoring in patients undergoing elective craniotomy

Protocol summary

Study aim

Comparison of the effect of mannitol and hypertonic sodium administration to reduce ICP on hemodynamic parameters under LiDCO monitoring in patients under elective craniotomy

Design

This randomized clinical trial will be conducted in 1400-1401 at Sinai Hospital. In this study, adult patients aged 18 to 65 years with ASA status I and II who are to undergo elective craniotomy will be evaluated. Patients enrolled in the study will be randomly divided into two groups: mannitol (receiving 5 ml/kg mannitol 20%) or hypertonic sodium (receiving 3 mg/kg hypertonic serum 5%).

Settings and conduct

This randomized clinical trial will be performed in 1400 at Sina Hospital in the neurosurgery room by the anesthesia department in collaboration with the neurosurgery department. Patients admitted to the study will be randomly divided into mannitol or hypertonic sodium during craniotomy to control cerebrospinal fluid.

Participants/Inclusion and exclusion criteria

Adult patients aged 18 to 65 years with ASA status I and II undergoing elective craniotomy. exclude criteria: previous history of cranial surgery, pregnancy, obesity (BMI above 40), sodium level > 160, Hb < 10, treated patients With hyperosmotic fluids 24 hours before surgery.

Intervention groups

Patients enrolled in the study will be randomly divided into two groups: mannitol (receiving 5 ml/kg mannitol 20%) or hypertonic sodium (receiving 3 mg/kg hypertonic serum 5%).

Main outcome variables

systolic blood pressure, diastolic blood pressure, MAP, PPV pulse pressure changes, SVV stroke volume changes, cardiac output CO, cardiac index CI, SV stroke

volume, systemic vascular resistance SVR will be registered. Oxygenation recorded during monitoring based on PaO₂, PaCO₂, HCO₃, pH, SaO₂

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170805035510N7**

Registration date: **2022-01-20, 1400/10/30**

Registration timing: **prospective**

Last update: **2022-01-20, 1400/10/30**

Update count: **0**

Registration date

2022-01-20, 1400/10/30

Registrant information

Name

Pejman Pourfakhr

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4466 3963

Email address

pourfakhr@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of mannitol and hypertonic sodium administration to reduce ICP on hemodynamic parameters under LiDCO monitoring in patients undergoing elective craniotomy

Public title
Comparison of the effect of mannitol and hypertonic sodium administration to reduce ICP on hemodynamic parameters

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
ASA class 1,2 Elective Craniotomy
Exclusion criteria:
previous craniotomy pregnancy morbid obesity(BMI>40)
Na>160 Hb<10 Patients treated with hyperosmotic fluids
24 hours before surgery

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the website www.sealedenvelope.com/, quadruple blocks were generated for randomization. The number of generated blocks will be 12 (sample size 44). The website generates blocks randomly (taking into account the number of study groups They are equal in each block) then they are provided to the person as Excel output. The determination of entry to the study is done based on the blocks made in order to intervention or control groups based on generated blocks.

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 Tehran University of Medical Sciences and Health services

Street address

Tehran University of Medical Sciences, Central Building, Ghods Ave., Keshavarz Blvd.

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Tehran

Province

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Postal code

1417653761

Approval date

2021-04-26, 1400/02/06

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1400.016

Health conditions studied

1

Description of health condition studied

Craniotomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pulse pressure variation

Timepoint

Every 20 min

Method of measurement

Advance Hemodynamic Monitoring

2

Description

Stroke volume variation

Timepoint

Every 20 min

Method of measurement

Advance Hemodynamic Monitoring

Secondary outcomes

1

Description

Acidosis

Timepoint

Every 1 hour

Method of measurement

Blood Gas Analysis

Intervention groups

1

Description

Intervention group: Receive 5 ml / kg mannitol 20% by slow intravenous injection after induction of anesthesia

Category

Treatment - Drugs

2

Description

Intervention group: Receive 3 mg / kg of hypertonic serum 5.% by slow intravenous injection after induction of anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Pejman Pourfakhr

Street address

Sina hospital, Hasan abad Square.

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1136746911

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pourfakhr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohamad Ali Sahraian

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Pejman Pourfakhr

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Fax**Email**

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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

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

Statistical Analysis Plan

Not applicable

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

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

Data Dictionary

Not applicable

Title and more details about the data/document

Laboratory information and monitoring device

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Use of the data is subject to the permission of all beneficiaries of this trial

From where data/document is obtainable

Pejman Pourfakhr - Tehran, Imam Khomeini St., Sina Hospital, Anesthesia Department, Tel: 02163128

What processes are involved for a request to access data/document

At the request of the Vice Chancellor for Research, Department of Anesthesiology, Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Pejman Pourfakhr

Position

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Latest degree

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