# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Nov 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.

**City**

Tehran

**Province**

Tehran

**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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## 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**
Tehran University of Medical Sciences, Keshavarz Blvd
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vcr@tums.ac.ir
**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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**