

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of effect of preoperative infusion of mannitol vs hypertonic saline on ICP and inflammatory biomarkers in brain tumor patients undergo craniotomy at Sina hospital, a randomized clinical trial

Protocol summary

Study aim

We estimate a reduction in biomarkers in patients under hypertonic saline infusion. It seems helpful to evaluate the effectiveness of these 2 osmotic fluids about anti-inflammatory effects in brain tumor patients.

Design

Randomization method: Block balanced method sample size: 60 patients

Settings and conduct

This study was conducted in Neurosurgery Sina Hospital. The study is double-blind. The patient was anesthetized and didn't conscious about the fluid prescribed. The neurosurgeon has not been informed of the type of fluid infused before surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: supratentorial new onset brain tumor patients without history of craniotomy or metastasis. patient's age should be 18 to 80. exclusion criteria: metastasis, age above 80 and under 18, uncontrolled blood pressure, diabetes melitus, severe cardiopulmonary disorders, nephrotic syndrome, GCS < 6

Intervention groups

Patients were divided into two intervention and control groups after reviewing the conditions for entering the study. Mannitol control group at a dose of 1 g / kg and another 2-3 mg / kg of hypertonic saline was infused before induction of anesthesia. Before incision, a blood sample was taken from the patient's arterial line. Immediately after opening Dura and before CSF drainage, intracranial pressure was reported by the neurosurgeon: low, moderate, high. The patient was monitored for hemodynamic conditions up to 72 hours after surgery and after 72 hours a blood sample was taken and stored at -80 C until all samples were collected to measure the S100B blood factor with a diagnostic kit.

Main outcome variables

S100B as a neuro inflammatory marker , urine output

and hemorrhage volume during surgery and duration of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161126031091N2**

Registration date: **2018-09-11, 1397/06/20**

Registration timing: **retrospective**

Last update: **2018-09-11, 1397/06/20**

Update count: **0**

Registration date

2018-09-11, 1397/06/20

Registrant information

Name

Mahsa Babaie

Name of organization / entity

Tehran university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

this project is under financial support of pharmaceutical science research center (PSRC)

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

2017-10-07, 1396/07/15

Actual recruitment end date

2018-03-06, 1396/12/15

Trial completion date

empty

Scientific title

Evaluation of effect of preoperative infusion of mannitol vs hypertonic saline on ICP and inflammatory biomarkers in brain tumor patients undergo craniotomy at Sina hospital, a randomized clinical trial

Public title

Effect of mannitol and hypertonic saline on brain tumor

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Supratentorial brain tumor patients without history of craniotomy New onset brain tumor Age above 18 and under 80

Exclusion criteria:

Metastatic brain tumor Renal failure (Cr>1.5) Nephrotic syndrome Heart rate <60 Diabetes melitus Severe cardiopulmonary disorders Uncontrolled high blood pressure Age under 18 and above 80 Glasco Coma Scale under 6

AgeFrom **18 years** old to **80 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample sizeTarget sample size: **60**Actual sample size reached: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Our randomization method was block balance method. we used randomized number table to apply method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient who undergoes craniotomy will be unconscious while we infuse the fluid, so this side will be considered blind. the neurosurgeon will not know which osmotic solution we would use before start of the surgery. so this RCT will be double blind.

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

Street address

Tehran university of medical sciences, 16th Azar street, Keshavarz Blvd, Tehran, Iran

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Province

Tehran

Postal code

1417653761

Approval date

2017-10-03, 1396/07/11

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3609

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

brain tumor

ICD-10 code

G96.9

ICD-10 code description

G96.9 is a billable/specific ICD-10-CM code that can be used to indicate a diagnosis for reimbursement purposes.

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

S100B (a biomarker)

Timepoint

operation day (before infusion of osmotic fluid) and 72 hours after surgery

Method of measurement

S100B measuring with ELISA kit (Biovender)

Secondary outcomes**1****Description**

urine output (ml) during the operation

Timepoint

at the end of the operation

Method of measurement

by measuring of urine output collected in urine bag

2

Description

bleeding volume(ml) during operation

Timepoint

at the end of the operation

Method of measurement

by measuring of bottle and used gauzes during the surgery.

3

Description

operating time

Timepoint

at the end of the operation

Method of measurement

by measuring time based on hours and minutes of start and end of operation

Intervention groups

1

Description

patients in intervention group received 2-3 meq/kg hypertonic saline 5%. they were taken a blood sample (about 3 cc) before being administered hypertonic saline and 72 hours after the operation. all samples were stored in a freezer until measuring by S100B laboratory kit.

Category

Treatment - Drugs

2

Description

Control group: patients received 1 g / kg Mannitol 20%.they were taken a blood sample (about 3 cc) before being administered Mannitol and 72 hours after the operation. all samples were stored in a freezer until measuring by S100B laboratory kit.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Mahsa Babaie

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Hassan Abad Sq, Imam Khomeini St,Tehran,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohammad Ali Sahraian

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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

Mahsa Babaie

Position

PharmD student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Dr. Mojtaba Mojtahedzadeh
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Professor, pharmacotherapist(clinical care medicine)
Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there is no more information,

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Patient's profile could be publishable without their names and profile number.

When the data will become available and for how long

Start the access period 6 months after publishing the results

To whom data/document is available

Researchers working in academic, scientific institutions and hospitals.

Under which criteria data/document could be used

All academic members requesting information about unidentified data.

From where data/document is obtainable

Applicants can submit their application through the email address of the person in charge of the study so that the data file will be sent to them via email within a maximum of one week.

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

Applicants can submit their application through the email address of the person in charge of the study so that the data file will be sent to them via email within a maximum of one week.

Comments