Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 fluid 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)

Phone
+98 64120

Email address
mhs.babaie@student.tums.ac.ir

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
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target 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
City
Tehran
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 mesuring 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
Street address
Hassan Abad Sq, Imam Khomeini St,Tehran,Iran
City
Tehran
Province
Tehran
Postal code
١١٣٦٧٤٦٩١١
Phone
+98 21 6634 8500
Email
mhs.babaie@student.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Mohammad Ali Sahraian
Street address
,6th floor,Research and technology institute,Central building of Tehran university of medical sciences,Qods St,Keshavard Blv.Tehran,Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
Email
msahrai@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
Mahsa Babaie
Position
PharmD student
Latest degree
A Level or less
Other areas of specialty/work
Street address
Tehran
City
Tehran
Province

Tehran
Postal code
1417653761
Phone
00
Fax
Email
mhs.babaie@student.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran university of medical sciences
Full name of responsible person
Dr. Mojtaba Mojtahedzadeh
Position
Professor, pharmacotherapist(clinical care medicine)
Latest degree
Subspecialist
Other areas of specialty/work
Medical Pharmacy
Street address
Sina hospital and faculty of pharmacy(TUMS)
City
Tehran
Province
Tehran
Postal code
١١٣٦٧٤٦٩١١
Phone
00
Fax
Email
mojtahed@sina.tums.ac.ir
Web page address

Person responsible for updating data

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
Medical Pharmacy
Street address
faculty of pharmacy,Tehran university of medical sciences,Poursina St,Keshavarz Blv,Tehran,Iran
City
Tehran
Province
Tehran
Postal code
١۴١٧۶١۴۴١١
Phone
00
Fax
Email
mhs.babaie@student.tums.ac.ir
Web page address

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