Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effects of the simultaneous use of Voluven (hydroxyethyl starch 0.4.130) plus 20% mannitol compared to Voluven plus 3% hypertonic saline on blood coagulation using PFA-100 in patients who are candidates for surgery for supratentorial brain tumors.

Protocol summary

Study aim

Comparison of the effects of simultaneous use of Voluven and mannitol with Volvon and hypertonic saline 3% on blood coagulation using PFA-100 in patients who are candidates for surgery for supratentorial brain tumors.

Design

Clinical trial, without control group, with parallel groups, double-blind, randomized, phase 3 on 30 patients, randomization using dice rolling

Settings and conduct

After obtaining informed consent, all patients over 18 years of age who are candidates for primary surgery of supratentorial tumors referring to the operating room of the government teaching hospital are included in the study. Patients will not be included in the study if they have an uncontrollable underlying disease, diseases affecting coagulation or taking drugs affecting coagulation. In group M, mannitol is injected at the rate of 1 g/kg and over a period of 20 minutes. In group S, 3% hypertonic saline at the rate of 5 ml/kg (creating osmolality equal to mannitol) will also be injected during 20 minutes. The blood sample is sent to measure blood gases and platelet function 20 minutes after the injection of 3% mannitol and hypertonic saline solutions.

Participants/Inclusion and exclusion criteria

All patients over 18 years of age who are candidates for supratentorial tumor surgery are included in the study after obtaining informed consent. People with uncontrolled underlying diseases or diseases affecting coagulation or taking drugs affecting blood coagulation will not be included in the study.

Intervention groups

In group M, mannitol is injected at the rate of 1 g/kg and over a period of 20 minutes. In group S, 3% hypertonic saline at the rate of 5 ml/kg will also be injected during 20 minutes.

Main outcome variables

Comparison of the effects of mannitol with hypertonic saline 3% on blood coagulation using PFA-100 in patients who are candidates for surgery of supratentorial brain tumors.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210506051200N2**
Registration date: **2023-04-05, 1402/01/16**
Registration timing: **retrospective**

Last update: **2023-04-05, 1402/01/16**
Update count: **0**

Registration date

2023-04-05, 1402/01/16

Registrant information

Name
Sohrab Salimi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2221 2058
Email address
ssalimi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-31, 1401/10/10

Expected recruitment end date
2023-03-30, 1402/01/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effects of the simultaneous use of Voluven (hydroxyethyl starch 0.4.130) plus 20% mannitol compared to Voluven plus 3% hypertonic saline on blood coagulation using PFA-100 in patients who are candidates for surgery for supratentorial brain tumors.

Public title
Comparing the effects of mannitol and hypertonic saline on blood coagulation in brain tumor patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Consent to study Age above 18 years
Exclusion criteria:
Absence of heart failure History of diseases affecting coagulation Recent use of drugs affecting coagulation Absence of renal failure Absence of liver failure
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are grouped using a simple randomization method by rolling dice. In this way, if the tap comes, the S group will be selected and if the line comes, the M group will be selected.
Blinding (investigator's opinion)
Double blinded
Blinding description
Before performing anesthesia, an anesthesiologist who will not be involved in the next stages of the study will determine the patient's group using dice and the patient will receive the drug intervention according to his/her group. The anesthesiologist in charge of the patient will record the information and deliver it to the researcher in a sealed envelope.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The ethical commite of Shahid Beheshti University of Medical Science
Street address
Shahid Beheshti University of Medical Sciences, Shahid Arabi St., Yemen St., Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2018-11-04, 1397/08/13
Ethics committee reference number
IR.SBMU.RETECH.REC.1397.621

Health conditions studied

1

Description of health condition studied
Supratentorial tumor
ICD-10 code
D43.0
ICD-10 code description
Neoplasm of uncertain behavior of brain, supratentorial

Primary outcomes

1

Description
closing time
Timepoint
Twenty minutes after drug injection in each of the two groups
Method of measurement
Using PFA100 laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the mannitol (M) group, the initial blood sample is sent before anesthesia and then after 20 minutes of mannitol injection for PFA-100 measurement.

Category

Treatment - Drugs

2

Description

Intervention group: In the hypertonic saline (S) group, the initial blood sample is sent before anesthesia and then after 20 minutes of mannitol injection for PFA-100 measurement.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان امام حسین

Full name of responsible person

سهراب سلیمی

Street address

تهران، خیابان شهید مدنی، بیمارستان امام حسین

City

تهران

Province

Tehran

Postal code

1617763141

Phone

+98 21 7756 7840

Email

ssalimi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

University Blvd, Velenjak

City

tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 2243 9781

Email

mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sohrab Salimi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

No. 1, Nilofar Alley, Bahram North, Pourheidari St., Quitarieh

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 2221 2058

Fax

Email

ssalimi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sohrab Salimi

Position

Associate professor

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Phone
+98 21 2221 2058
Fax
Email
ssalimi@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sohrab Salimi
Position
Associated Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Imam Hossein Hospital, Shahid Madani St
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7756 7840
Email
ssalimi@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data can be shared after de-identifying individuals.
When the data will become available and for how long
A year after the publication of the article
To whom data/document is available
All jobs
Under which criteria data/document could be used
All non-personal information related to the research can be accessed by contacting the corresponding author.
From where data/document is obtainable
E-mail to the corresponding author
What processes are involved for a request to access data/document
Email submission and review by the responsible author
Comments