

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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@sbm.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 committee 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

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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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

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

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Person responsible for updating data

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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