Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison effects of Mannitol 20% and Hypertonic Saline 5% on Electrolyte Balance during Brain Tumor Surgery

Protocol summary

Summary

After obtaining written informed consent from eligible patients, and getting an approval from Ethics committee of Ahvaz Jundishapur University of Medical Sciences, a double-blind prospective, randomized study will be done among patients with Brain Tumor Surgery. Thirty four patients scheduled for general anesthesia will be received midazolam one mg intravenously five min before entering the operating room. Premedication will perform with fentanyl two micro gram/kg. General anesthesia will perform with 4 mg/kg sodium thiopental. Inclusion criteria: The parent's consent, Age between 18 and 60 years old, ASA class I. Exclusion criteria: Previous complications with general anesthesia, Heart disease, Metabolic disorders, Chronic alcohol consumption and Brain herniation. Patients will be randomly allocated into two groups according to table of random numbers. Groups "one" and "two" will be received 5 ml/Kg mannitol(20%) Intravenous or 2.5 ml/Kg hypertonic saline(5%) Intravenous at the beginning of the surgery, respectively. The amount of electrolytes (sodium, potassium, chloride) and bicarbonate will be measured before surgery, 120 minutes after the start of surgery and at the end of the surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060222535N1**
Registration date: **2015-06-16, 1394/03/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-06-16, 1394/03/26

Registrant information

Name
Hengameh Rajabzadeh
Name of organization / entity
Ahvaz Jundishapur University of Medical Science
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-10-01, 1394/07/09

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effects of Mannitol 20% and Hypertonic Saline 5% on Electrolyte Balance during Brain Tumor Surgery

Public title

Comparison effects of Mannitol 20% and Hypertonic Saline 5% on Electrolyte Balance during Brain Tumor Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: - The parent's consent - Age between

18 and 60 years old - ASA class I Exclusion criteria: - Previous complications with general anesthesia - Heart disease - Metabolic disorders - Chronic alcohol consumption - Brain herniation

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Ahvaz Jundishapur University of Medical Sciences

Street address

No. 21, Ave. 1, Golestan Blvd.

City

Ahvaz

Postal code

6135733777

Approval date

2015-05-09, 1394/02/19

Ethics committee reference number

IR.AJUMS.REC.1394.59

Health conditions studied

1

Description of health condition studied

Neoplasm of brain

ICD-10 code

C71.9

ICD-10 code description

Malignant neoplasm of brain(unspecified)

Primary outcomes

1

Description

Serum Sodium

Timepoint

Before surgery, 120 minutes after the start of surgery and at the end of the surgery

Method of measurement

Laboratory

2

Description

Serum Pottasium

Timepoint

before surgery, 120 minutes after the start of surgery and at the end of the surgery

Method of measurement

Laboratory

3

Description

Serum Chlorine

Timepoint

Before surgery, 120 minutes after the start of surgery and at the end of the surgery

Method of measurement

Laboratory

4

Description

Bicarbonate

Timepoint

Before surgery, 120 minutes after the start of surgery and at the end of the surgery

Method of measurement

Laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Mannitol(20%): Dose: 5 ml/kg Number of using: Once Factory name: Razi Manufacturing Country's Name: Iran Location prescribed: Intravenous Injection Administration time: At the beginning of the surgery

Category

Treatment - Drugs

2

Description

Hypertonic Saline(5%): Dose: 2.5 ml/kg Number of using: Once Factory name: Alborz Manufacturing Country's

Name: Iran Location prescribed: Intravenous Injection Administration time: At the beginning of the surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Educational Hospital

Full name of responsible person

Dr, Nozar Nasajian

Street address

No. 307, Kokab Street, Masters Alley, Golestan Blvd.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Mostafa Feghhi

Street address

No. 21, Ave. 1, Golestan Blvd.

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Hengameh Rajabzadeh

Position

Resident of Anesthesia

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Hengameh Rajabzadeh

Position

Resident of Anesthesia

Other areas of specialty/work

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty