

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Comparison of the efficacy of hypertonic saline 5% with mannitol 20% on cerebral edema in ischemic and hemorrhagic stroke patients: a randomized clinical trial

Protocol summary

Study aim

To compare of the efficacy of hypertonic saline 5% with mannitol 20% on cerebral edema in ischemic and hemorrhagic stroke patients

Design

This is a Phase III randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the Besat Hospital in Hamadan city, involving 100 eligible patients. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 80 years Stroke GCS score between 3 and 8 Systolic blood pressure greater than 90 mmHg Having at least one pupillary reaction Exclusion criteria: Anuria or creatinine higher than 2.5 Convulsions Hypoxia

Intervention groups

Intervention group: Mannitol 20% first with a dose of 1.5 gr/kg, then 100 ml every 4 hours within 15 to 20 minutes and repeating it until the patient regains consciousness
Control group: Hypertonic saline 5% with a dose of 3 to 5 ml/kg and the same dose every 6 hours within 15 to 20 minutes and repeating it until the patient regains consciousness

Main outcome variables

Primary outcome: Cerebral edema

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N480**

Registration date: **2023-08-23, 1402/06/01**

Registration timing: **prospective**

Last update: **2023-08-23, 1402/06/01**

Update count: **0**

Registration date

2023-08-23, 1402/06/01

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2023-11-06, 1402/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of hypertonic saline 5% with

mannitol 20% on cerebral edema in ischemic and hemorrhagic stroke patients: a randomized clinical trial

Public title

Comparison of the efficacy of hypertonic saline 5% with mannitol 20% on cerebral edema in ischemic and hemorrhagic stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 80 years Stroke GCS score between 3 and 8 Systolic blood pressure greater than 90 mmHg Having at least one pupillary reaction

Exclusion criteria:

Anuria or creatinine higher than 2.5 Convulsions Hypoxia

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

Blinding (investigator's opinion)

Not 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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

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Province

Hamadan

Postal code

65157838695

Approval date

2023-04-07, 1402/01/18

Ethics committee reference number

IR.UMSHA.REC.1402.021

Health conditions studied

1

Description of health condition studied

Cerebellar stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

Cerebral edema

Timepoint

Before the intervention and after consciousness

Method of measurement

By using MRI

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mannitol 20% first with a dose of 1.5 gr/kg, then 100 ml every 4 hours within 15 to 20 minutes and repeating it until the patient regains consciousness

Category

Treatment - Drugs

2

Description

Control group: Hypertonic saline 5% with a dose of 3 to 5 ml/kg and the same dose every 6 hours within 15 to 20 minutes and repeating it until the patient regains consciousness

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital in Hamadan city

Full name of responsible person

Aliakbar Sooleymanloo

Street address

Besat Hospital, Shahed Square

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Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Aliakbar Sooleymanloo

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Neurologist

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available