

# 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

Hamadan

#### 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

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3364 0030

**Email**

aliakbarsoleymanlo@gmail.com

## 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

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

info.research@umsha.ac.ir

**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

**Street address**

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

aliakbarsoleymanlo@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Mjtaba Khazaei

**Position**

Neurologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

m.khazaei@umsha.ac.ir

## 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

**Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

**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