

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Comparison of the effect of hyper-tonic saline with placebo on mortality and three-months hospital prognosis in patients with severe ischemic stroke

#### Protocol summary

##### Study aim

Determination of the effect of placebo hyper-tonic saline on mortality and hospital 3-months outcome in patients with severe ischemic stroke

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 100 patients. Patients will be allocated into two groups using a permuted balanced block randomization method with the size of blocks 4 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>).

##### Settings and conduct

The study is performed in Shahid Beheshti Hospital, Department of Neurology, Qom, . In this study, it is a randomized clinical trial in one group will be treated with hypertonic saline and one group will be treated with placebo (normal saline). In the intervention group treated with hyper-tonic saline at a dose of 50 mg every 8 hours with daily sodium checks and osmolarity and its effect on the severity of stroke in the days before treatment, in the same way to patients entering the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Moderate to severe ischemic stroke 2- Age between 18 and 80 years 3. No previous use of hypertonic saline and other serums in a recent month before the onset of symptoms Exclusion criteria 1- Having a previous chronic disease that interferes with the functional evaluation of patients, such as cancers, 2- liver or kidney or heart failure, 3 -Chronic infection 4- Dissatisfaction

##### Intervention groups

The first group receives standard treatment and placebo, which is very similar to our drug, and the second group receives hyper-tonic saline in addition to standard treatment.

#### Main outcome variables

1. Hospital death 2. Duration of hospitalization 3. interval between hospitalization and discharge 4- Patients recovery in 3 months follow-up

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190311043008N1**

Registration date: **2021-02-19, 1399/12/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-02-19, 1399/12/01**

Update count: **0**

##### Registration date

2021-02-19, 1399/12/01

##### Registrant information

##### Name

Ehsan Sharifipour

##### Name of organization / entity

Qom university of medical Sciences, Neuroscience Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3285 2720

##### Email address

sharifipour.e@muq.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-11-10, 1399/08/20

##### Expected recruitment end date

2021-11-10, 1400/08/19

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of hyper-tonic saline with placebo on mortality and three-months hospital prognosis in patients with severe ischemic stroke

**Public title**  
The effect of hyper-tonic saline serum on the outcome of patients with severe stroke

**Purpose**  
Health service research

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Moderate to severe ischemic stroke Age between 18 and 80 years Agreed to participate in the study No previous use of hyper-tonic saline and other serums in the last month before the onset of symptoms Hospitalized in the neurology ward of Shahid Beheshti Hospital,  
**Exclusion criteria:**  
 Having a previous serious chronic disease that interferes with the functional evaluation of patients, such as cancers, Liver , kidney , heart failure, Chronic infection Dissatisfaction

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

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients will be allocated into two groups using apermuted balanced block randomization method with the size of blocks 4 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Concealment is also guaranteed due to the use of specific codes that are obtained by the website.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Double blind: in addition to participants, investigators or the assessors of the outcomes are aslo unaware of the study groups.

**Placebo**  
Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee ofQom University of Medical Sciences

##### Street address

No. 83, Jahad Daneshgahi Ave., Alghadir Blvd., Deputy of Research

##### City

Qom

##### Province

Ghoum

##### Postal code

3716993456

#### Approval date

2020-07-21, 1399/04/31

#### Ethics committee reference number

IR.MUQ.REC.1399.171

## Health conditions studied

### 1

#### Description of health condition studied

Sever Ischemic stroke

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Death

#### Timepoint

During Hospitalization

#### Method of measurement

Physician diagnosis

### 2

#### Description

Patient recovery in quarterly follow-up

#### Timepoint

Before starting treatment on days 5, 10, 30 and three months after starting treatment with hyper-tonic saline

#### Method of measurement

The initial checklist form includes: type of stroke, frequency of stroke, risk factors and clinical scoring score based on the National Institutes of Health Stroke Scale (NIHSS) and Modified Rankin Scale (MRS).

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients who receive packages including standard treatments plus hypertonic saline serum made by Shahid Ghazi Company. Initial dose of 200 ml of serum 5% hyper-tonic saline then 50 ml every hour for up to seven days. Provided that sodium ; Less than 155 mg / l, and blood osmolality less than 320 mg / dL.

#### Category

Other

### 2

#### Description

Control group: Patients who receive a package containing standard treatments plus normal saline serum will be considered group 1. The package containing standard treatments plus normal saline serum will receive 200 ml, then 50 ml every hour for up to seven days.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hospital

##### Full name of responsible person

Dr Ehsan Sharifipour

##### Street address

Shahid Chamran Ave.,

##### City

QOM

##### Province

Ghoum

##### Postal code

3719964797

##### Phone

+98 21 3612 2000

##### Email

Sharifipour.e@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ghoum University of Medical Sciences

##### Full name of responsible person

Sharifipour Ehsan

#### Street address

Shahid Beheshti Ave

#### City

Qom

#### Province

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#### Postal code

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#### Phone

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#### Email

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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

Ghoum 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

Ghoum University of Medical Sciences

##### Full name of responsible person

Sharifipour Ehsan

##### Position

Assistant Professor of Neurology

##### Latest degree

Specialist

##### Other areas of specialty/work

Neuroscience

##### Street address

Shahid Beheshti Ave

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##### Phone

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##### Email

Sharifipour.e @muq.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ghoum University of Medical Sciences  
**Full name of responsible person**  
Ehsan Sharifipour  
**Position**  
Assistant Professor of Neurology  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Province**  
Ghoum  
**Postal code**

3716993456

### Phone

+98 25 3285 2720

### Email

Sharifipour.e@muq.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

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Information on the main outcome is available

### When the data will become available and for how long

Access period starts 6 months after the results are published.

### To whom data/document is available

Will be allowed for neurologists from medical universities.

### Under which criteria data/document could be used

Collaborators at other medical universities will be allowed to comment on the consequences of the results.

### From where data/document is obtainable

Contact the main executor of the project in Qom University of Medical Sciences by email.

### What processes are involved for a request to access data/document

The applicant must be a partner in the project and in contact with the executor. After reviewing the application, the executor will send it by email within a week.

### Comments