Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 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 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/).

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,Neurosience Research Center

Country

Iran (Islamic Republic of)

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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.,
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3719964797
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Sharifipour Ehsan
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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
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Person responsible for scientific inquiries

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Position
Assistant Professor of Neurology

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Person responsible for updating data

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Assistant Professor of Neurology

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Specialist

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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
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