

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of intravenous magnesium sulfate in improvement of disability resulted from acute ischemic stroke in patients referred to Ahvaz Golestan hospital

Protocol summary

Summary

(1) Objectives: This study proposes an available and inexpensive method to reduce disabilities resulting from acute ischemic stroke which has a high prevalence among the general population. (2). Design: The present study was a double-blind clinical trial. (3) Setting and conduct: After explaining the process and obtaining informed consent, patients referred to Ahvaz Golstan hospital with ischemic stroke in the middle cerebral artery were randomly placed in drug receiver (magnesium sulfate) and placebo groups.(4) Patients included were between 45 to 75 years old, had experienced ischemic stroke less within the past 24 hours, and had neural symptoms. In addition, they had no evidence of a brain hemorrhage in primary brain CT scan, and no prior chronic renal failure, heart block, respiratory failure, or acute metabolic disorder. (5) Intervention: In the drug receiver group, in addition to main antiplatelet treatment (aspirin), for 5 days, 4 gram magnesium sulfate in 200 cc normal saline was infused, intravenously (loading dose). Then, 16 gr in 800 cc normal saline were infused every 24 hours. In the placebo group, for 5 days, 800 cc normal saline was infused intravenously every 24 hours. (6) Main outcome measures (variables): In addition to the first visit, patients were visited at the end of the first and third month. In each case, mNIHS, mRankin scale scores, and death rates were recorded. Finally, we compared disability resulting from acute ischemic stroke (first day, first month, and third month) using above criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060712781N4**
Registration date: **2016-04-03, 1395/01/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-03, 1395/01/15

Registrant information

Name

Davood Kashipazha

Name of organization / entity

Ahvaz JodndiShapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1374 3012

Email address

kashi-d@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

The cost of the project will be provided from Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of intravenous magnesium

sulfate in improvement of disability resulted from acute ischemic stroke in patients referred to Ahvaz Golestan hospital

Public title

Effect of magnesium sulfate in acute ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with the following conditions were included: 45 to 75 years old patients with ischemic stroke within the middle cerebral artery; patients who had symptoms of focal neurological deficits on arrival; ischemic stroke had occurred within past 24 hours; Modified National Institutes of Health Stroke Scale was between 5 to 25 on arrival; no evidence of a brain hemorrhage in primary CT scan. Exclusion criteria: patients with the following conditions were excluded: prior chronic renal failure or serum Creatinine level above 3 mg/dl; pregnancy; prior heart block or its evidences in initial ECG; prior respiratory failure or oxygen saturation below 90% or respiratory rate below 12 or above 24 per minute; prior neurodegenerative, demyelinating, muscular diseases and brain tumor; acute metabolic disorder (magnesium, sodium and potassium level); life-threatening diseases which may lead to death in the next three months; and patients who need help in daily activities and walking.

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of the Ahvaz Jundishapur University of Medical Sciences

Street address

Ethics committee, Research center, Ahvaz Jundishapur University of Medical, University town, Golestan, Ahvaz, Khoozestan

City

Ahvaz

Postal code**Approval date**

2015-03-07, 1393/12/16

Ethics committee reference number

IR.AJUMS.REC.1394.16

Health conditions studied**1****Description of health condition studied**

occlusion of middle cerebral artery

ICD-10 code

I66.0

ICD-10 code description

Occlusion and stenosis of middle cerebral artery

2**Description of health condition studied**

disability of cerebral infarction

ICD-10 code

I69.3

ICD-10 code description

Sequelae of cerebral infarction

Primary outcomes**1****Description**

Disability of acute ischemic stroke

Timepoint

Before intervention. 1 month and 3 month after intervention

Method of measurement

mRankin Scale Score and mNIHSS score

Secondary outcomes**1****Description**

Serum level of magnesium sulfate

Timepoint

Before intervention and the last day of intervention

Method of measurement

Blood sampling

Intervention groups**1****Description**

Intervention: Magnesium sulfate vial 4 gram in 200cc

normal saline loading dose in 20 minutes intravenous infusion then 16 gram in 800cc normal saline maintenance dose intravenous infusion during 24 hour till 5 days

Category

Treatment - Drugs

2**Description**

Placebo: Serum normal saline 800cc intravenous infusion during 24 hours till 5 days

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan Hospital

Full name of responsible person

Davood Kashipazha, Assistant Professor of Neurology

Street address

Neurology Ward, Golestan Hospital, Ahvaz, Khoozestan

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

Nader Saki

Street address

Research center, Central organization, Ahvaz Jundishapur University of Medical Sciences, University town, Golestan, Ahvaz, Khoozestan

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

Davood Kashipazha

Position

Assistant Professor of Neurology

Other areas of specialty/work**Street address**

Department of Neurology, Golestan hospital, Ahvaz

City

Ahvaz

Postal code**Phone**

+98 61 3374 3012

Fax**Email**

dakashi47@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Davood Kashipazha

Position

Assistant Professor of Neurology

Other areas of specialty/work**Street address**

Department of Neurology, Golestan hospital, Ahvaz, Khoozestan

City

Ahvaz

Postal code**Phone**

+98 61 3374 3012

Fax**Email**

dakashi47@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Asieh Mehramiri

Position

Assistant of Neurology

Other areas of specialty/work**Street address**

Department of Neurology, Golestan Hospital,

Golestan, Ahvaz, Khoozestan

City

Ahvaz

Postal code

Phone

+98 61 3374 3012

Fax

Email

mehramiri.ac@gmail.com

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