Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Ahwaz 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 Sciencs

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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 Scienses
Street address
Ethics committiee, 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 Scienses

Full name of responsible person

Davood Kashipazha

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Other areas of specialty/work

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Person responsible for updating data

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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