

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of intravenous magnesium sulphate in clinical improvement of patients, with acute stroke

#### Protocol summary

##### Summary

Background: This study evaluated the effect of intravenous magnesium sulphate in clinical improvement of the patients with acute stroke. In various studies, there is a lot of information about the use of magnesium sulphate in different conditions of brain ischemia. While neuroprotective effects of magnesium sulphate as a neuroprotective agent has been demonstrated in focal and global brain ischemia, in animal models, but the effect of this agent is still unclear. Methods: 80 patients (In this study, 47 percent of patients was female and 53 percent was male) of with acute ischemic stroke signs and symptoms lasting less than 12 hours were included in the study and were divided into two groups, 40 patients received 4 g of MgSO<sub>4</sub> over 15 minutes and then 16 g over the next 24 hours, and 40 patients were received placebo. Results: the results show that the rate of clinical improvement was better in group with magnesium sulphate, than the control group. The highest correlation of magnesium sulphate was associated with improvement of upper and lower muscle forces and aphasia and level of consciousness of patients results. The results showed that, in the group with magnesium sulphate, the patients with Grade III decreased and the patient with Grade II, I increased. After 2 weeks in this Group the patients with Grade III, decreased to 12.5 percent and the patients with Grade II and I, increased to 50 percent and 37.5 percent. (According to national institutes of health stroke scale). Conclusion: According to this study, magnesium sulphate, can be used as a neuroprotective agent in patients with acute stroke. Key words: magnesium sulphate, stroke, neuroprotective

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014060117945N1**

Registration date: **2014-07-20, 1393/04/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-07-20, 1393/04/29

##### Registrant information

###### Name

Ghasem Fattahzadeh Ardalani

###### Name of organization / entity

Ardabil University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Ardabil University of Medical Sciences

##### Expected recruitment start date

2013-08-21, 1392/05/30

##### Expected recruitment end date

2014-03-21, 1393/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of intravenous magnesium sulphate in clinical improvement of patients, with acute stroke

##### Public title

Evaluation of intravenous magnesium sulphate in clinical

improvement of patients, with acute stroke, in Ardabil Alavi hospital

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Age greater than 18 years old; Age less than 80 years old; onset of symptoms less than 12 hour .

Exclusion criteria: : Patient with chronic renal failure (more than 5.2); pregnant patients; patients with brain hemorrhage; age less than 18 years old; systolic blood pressure greater than 220 and diastolic lower than 90; patient with severe respiratory disease; patient with heart block; Patients with pre-existing neurological disease or progressive systemic disease that can impair neurological assessment.

### **Age**

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

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **80**

### **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**

Ardabil University of Medical Sciences

##### **Street address**

Department of Neurology, Alavi hospital

##### **City**

Ardebil

##### **Postal code**

#### **Approval date**

2013-07-14, 1392/04/23

#### **Ethics committee reference number**

9108

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Stroke

#### **ICD-10 code**

I64

#### **ICD-10 code description**

Accident - vascular, brain

## **Primary outcomes**

### 1

#### **Description**

Degree of limb paresis

#### **Timepoint**

Admission - three days later - two weeks later

#### **Method of measurement**

Standard questionnaire NIHSS

### 2

#### **Description**

Aphasia

#### **Timepoint**

Admission - three days later - two weeks later

#### **Method of measurement**

Standard questionnaire NIHSS

### 3

#### **Description**

level of consciousness

#### **Timepoint**

Admission - three days later - two weeks later

#### **Method of measurement**

Standard questionnaire NIHSS

## **Secondary outcomes**

### 1

#### **Description**

The rate of cerebral ischemia.

#### **Timepoint**

3 day later - 2 week later

#### **Method of measurement**

CT-scan

## **Intervention groups**

### 1

#### **Description**

In the control group the same amount of volume, not weight of normal saline solution over 15 minutes and then within 24 hours for patient was given.

#### **Category**

Placebo

## 2

### Description

In the intervention group magnesium sulfate vials has been given for the patient that have stroke in last 12 hour, 4 g intravenous magnesium sulfate in less than 15 minute and then 16 g within 24 hour has been given, the patients was controlled in admission and 3 day later and 2 week later.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Alavi hospital

**Full name of responsible person**

Dr Ghasem Fattahzadeh

**Street address**

Ardabil Alavi hospital

**City**

Ardebil

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Dr Ghasem Fattahzadeh Ardalani

**Street address**

Ardabil Alavi hospital

**City**

Ardebil

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ardabil 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**

Ardabil University of Medical Sciences

**Full name of responsible person**

Dr Ghasem Fattahzadeh Ardalani

**Position**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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## Person responsible for updating data

**Contact****Name of organization / entity****Full name of responsible person**

Masoud Ghasemi

**Position**

General Physician

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

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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*