

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluation of the protective effect of MGSO4 in Equation of the motion and lung inflammation following Amiodarone infusion in stroke

#### Protocol summary

##### Summary

Purpose: Evaluation of the protective effect of MGSO4 in Equation of the motion and lung inflammation following Amiodarone infusion in stroke. Design: This is a Randomized Controlled Clinical Trial Double Blind Prospective study that will be performed in one year interval in Sina and Baqiyatallah hospital. The patients will be assigned randomly to two groups after the consent form sign by a family member. Setting and conduct: The patients with confirmed stroke (by CT scan) will receive Amiodarone 300 mg as a bolus then 50 mg/hrs for 5 days. In the treatment group 15 cc (7.5 mg) of magnesium sulfate will be infused daily to each patient. In the control group 15 cc of placebo will be infused to each patient. Participant: The patients with confirmed stroke that consent form was signed by a family member and the patients who had atrial fibrillation and undergo treatment with amiodarone will be included in the study. Patients with Serum creatinine exceeding 2 mg/dl and presence of Hypermagnesemia will be excluded from the study. Intervention: Infusion of Magnesium sulfate to the intervention group and placebo to the control group. Main outcome measure: Measurement of MODS, APACHE II ,SOFA Score, Morbidity, Mortality ALT. AST. BUN, SCr, PH, Lactate, Total Bllirubin, Na, K, WBC, PLT, Hb IL6 IL8 SNSE S100B PAF PAI CAM 1 Elastin Fiber E-Selectin NGAL EGF TGF IgA IgG , FRC TLC MIV RV MVV , NIHSS and GCS before and after the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201701011165N16**

Registration date: **2017-01-29, 1395/11/10**

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

Last update:

Update count: **0**

##### Registration date

2017-01-29, 1395/11/10

##### Registrant information

###### Name

Yunes Panahi

###### Name of organization / entity

Baqiyatallah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8821 1524

###### Email address

yunespanahi@bmsu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor of research of Tehran university of medical sciences

##### Expected recruitment start date

2016-12-15, 1395/09/25

##### Expected recruitment end date

2017-12-16, 1396/09/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the protective effect of MGSO4 in Equation of the motion and lung inflammation following Amiodarone infusion in stroke

##### Public title

Evaluation of the protective effect of MGSO4 in Equation of the motion and lung inflammation following

Amiodarone infusion in stroke

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

\_Inclusion criteria: stroke confirmed by CT scan; Consent form was signed by family member; The patient was undergo treatment with amiodarone; The patient had Atrial fibrillation \_Exclusion criteria: Serum creatinin greater than 2 mg/dl; Hypermagnasemia occur in the patient; The patient do not receive treatment for more than 24 hours.

### **Age**

No age limit

### **Gender**

Both

### **Phase**

1

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

*No information*

### **Sample size**

Target sample size: **36**

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

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

Groups are randomly assigned to intervention and control group using blocks of four random design.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Baqiyatallah University of medical sciences

##### **Street address**

Mollasadra St - Sheikh bahaee

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2016-12-12, 1395/09/22

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

IR.BMSU.REC.1395.88

## **Health conditions studied**

### **1**

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

Stroke

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

I64

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

Stroke, not specified as haemorrhage or infarction

## **Primary outcomes**

### **1**

#### **Description**

Infarct size

#### **Timepoint**

Before and after of intervention

#### **Method of measurement**

CT Scan

### **2**

#### **Description**

Immunoglobulin G, Immunoglobulin A, S100B Protein, SNSE Protein

#### **Timepoint**

Before and after of intervention

#### **Method of measurement**

Elisa Kit

## **Secondary outcomes**

### **1**

#### **Description**

Mortality, Vascular resistance, Delirium, Mechanical ventilation index, Multi-Organ Dysfunction Score, APACHE II Score, SOFA Score, Candida Score, Hospitalization Period

#### **Timepoint**

Before and after of intervention

#### **Method of measurement**

Questionnaire

### **2**

#### **Description**

White blood cell count, platelet count, Hemoglobin, Alanine transaminase, Aspartate transaminase, Serum Creatinine, Serum Potassium, Serum Natrium, Serum Lactate, Total Serum Bilirubin, Blood PH

#### **Timepoint**

Before and after of intervention

#### **Method of measurement**

Blood and Serum Analysis

### **3**

#### **Description**

Interleukin 6, Interleukin 8, Platelet-activating factor, Plasminogen activator inhibitor-1, CAM-1 Protein, Elastin Fiber Protein, E-Selectin Protein, NGAL Protein, EGF Protein, TGF Protein

**Timepoint**

Before and after of intervention

**Method of measurement**

Elisa Kit

**4****Description**

Functional Residual Capacity, Respiratory Rate, Total Lung Capacity, Vital Capacity, Residual Volume, (Maximum Ventilatory Volume, Forced Expiratory Volume

**Timepoint**

During the study

**Method of measurement**

Ventilator

**5****Description**

Glasgow Coma Scale, National Institutes of Health Stroke Scale

**Timepoint**

During the study

**Method of measurement**

Questionnaire

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

Treatment group will receive 7.5 gr (15 cc) of magnesium sulfate SID for 5 days.

**Category**

Treatment - Drugs

**2****Description**

control group will receive 15 cc of placebo SID for 5 days.

**Category**

Placebo

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

Sina Hospital

**Full name of responsible person**

Dr Yunes Panahi

**Street address**

Hassan abad st - imam khomeini St

**City**

Tehran

**2****Recruitment center****Name of recruitment center**

Baqiyatallah hospital

**Full name of responsible person**

Dr Yunes Panahi

**Street address**

Mollasadra st - sheikh bahae st.

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of medical sciences (Vice Chancellor of research)

**Full name of responsible person**

Dr. Masoud Yunesian

**Street address**

6th floor, Central Organization of U of T, Keshavarz Blvd.

**City**

Tehran

**Grant name**

-

**Grant code / Reference number**

-

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of medical sciences (Vice Chancellor of research)

**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**

Baqiyatallah University of medical sciences

**Full name of responsible person**

Yunes Panahi

**Position**

Professor/ PharmD

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

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

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**Full name of responsible person**

Yunes Panahi

**Position**

Professor/ PharmD

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

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Tehran

**Postal code****Phone**

+98 21 8248 2503

**Fax****Person responsible for updating data****Contact****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*