Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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 Hypermagnasemia 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 fibrilation _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 bahaee 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
Mollasadra St.
City
tehran
Postal code
Phone
+98 21 8248 2503
Fax

Email
yunespanahi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
baiyatallah university of medical sciences
Full name of responsible person
Yunes Panahi
Position
Professor/ PharmD
Other areas of specialty/work
Street address
Mollasadra St. Sheikh bahaee st.
City
Tehran
Postal code
Phone
+98 21 8248 2503
Fax
Email
Yunespanahi@yahoo.com
Web page address

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