Clinical Trial Protocol
Iranian Registry of Clinical Trials
25 Apr 2020

Evaluation of the intravenous Magnesium sulfate effect in clinically improvement of patient with acute ischemic stroke

Protocol summary

Summary
Stroke is the leading cause of death and leading cause of disability in adult. The purpose of this clinical trial is Evaluation of the intravenous Magnesium sulfate effect in clinically improvement of patient with acute ischemic stroke. Patients will be randomly selected in neurology emergency of Farabi & Emam Reza hospital of Kermanshah. A group of 97 patients who clinically diagnosed acute ischemic stroke will be enrolled. The patients will be randomly allocated into one of two groups. We will administer Magnesium sulfate 4gr IV in 50 cc normal saline over 15 minutes followed by 16 gr in 100cc over 24 hours as a continuous infusion. The placebo group received equal volumes of normal saline alone. In all patients measure of global disability according to modified Rankin scale and NIH stroke scale will be assessed before of the treatment, 3days after treatment and discharge time. Finally, measure of global disability, amount of admition times and mortality rate in each group will be compared.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138901101856N2
Registration date: 2010-03-30, 1389/01/10
Registration timing: registered_while_recruiting

Last update: 
Update count: 0
Registration date 2010-03-30, 1389/01/10

Registrant information
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Recruitment status
Recruitment complete

Funding source
Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services

Expected recruitment start date
2010-03-11, 1388/12/20
Expected recruitment end date
2010-12-11, 1389/09/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the intravenous Magnesium sulfate effect in clinically improvement of patient with acute ischemic stroke

Public title
Evaluation of the Magnesium sulfate effect in ischemic stroke treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patient’s age between 40-95 years, last known well time within 12 hours of treatment initiation. Exclusion criteria: pregnancy-coma - heart block-chronic renal impairment- respiratory distress(24 < RR < 12 l, O2sat < 90)- systolic blood pressure <90 or >220mmhg- pre-existing neuralgic psychiatric or advanced systemic disease that confound neuralgical or functional outcome evaluation - hemorrhagic stroke - known recent stroke within past 30 days- rapidly resolving deficit

Age
From 40 years old to 95 years old
Gender
Both

Phase
2
Groups that have been masked  
No information

Sample size  
Target sample size: 97

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  
Kermanshah University of Medical Sciences and Health Servises Ethical Comitte

Street address  
Shahid Beheshti boulevard, Kermanshah

City  
Kermanshah

Postal code

Approval date  
empty

Ethics committee reference number  
88113

Health conditions studied

1
Description of health condition studied  
ischemic stroke

ICD-10 code  
I64

ICD-10 code description  
Stroke

Primary outcomes

1
Description  
measure of global disability

Timepoint  
before of the treatment ,3days after treatment and discharge time

Method of measurement  
according to modified Rankin scale

Secondary outcomes

1
Description  
mortality rate

Timepoint  
During admition times

Method of measurement  
patient' s medical documents

2
Description  
amount of admition times

Timepoint  
discharge time

Method of measurement  
patient' s medical documents

Intervention groups

1
Description  
Magnesium sulfate 4gr IV in 50 cc normal saline over 15 minutes followed by 16 gr in 100cc over 24 hours

Category  
Treatment - Drugs

2
Description  
equal volumes of normal saline

Category  
Placebo

Recruitment centers

1
Recruitment center  
Name of recruitment center  
Farabi Hospital of Kermanshah

Full name of responsible person  
Dr Dariush Afshari

Street address  
Ashayer boulevard, Dolat Abad, Kermanshah

City  
Kermanshah
Recruitment center
Name of recruitment center
Emam Reza Hospital of Kermanshah
Full name of responsible person
dr nasrin moradian
Street address
Sorkhelijeh, Kermanshah
City
Kermanshah

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services
Full name of responsible person
Dr Farid Najafi
Street address
Shahid Beheshti boulevard, Kermanshah
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Kermanshah
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, Kermanshah University of Medical Sciences and Health Services
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
Emam Reza Hospital
Full name of responsible person
Dr Dariush Afshari
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Neurologist/assistant professor/chairman
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Person responsible for updating data
Contact
Name of organization / entity
Emam Reza Hospital
Full name of responsible person
dr nasrin moradian
Position
Resident of neurology
Other areas of specialty/work
Street address
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Email
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
<table>
<thead>
<tr>
<th>Analytic Code</th>
<th>Data Dictionary</th>
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