Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Determination of mgso4 infusion effect for treatment of patient with acute pulmonary edema arrived rasol and sina hospital from khordad 1391 to khordad 1392

Protocol summary

Summary

Loop diuretics and thiazides are mainstay of cardiac acute pulmonary edema treatment.these drugs lead to excretion of Mg in urine, that decreasing Mg in intra and extracellular fluids. in past trial reported depletion of Mg in intra and extracellular fluid by one month treatment of lasix or hydrochlorotiazid. and so Mg depletion leads to dysrhythmia, neuromuscular dysfunction, hypokalemia and hypocalcemia that resistance to treatment in CHF patient under treatment by diuresis. also MgSo4 infusion (by depletion both catecholamine release and peripheral vascular resistance) leads to both repletion and improving noncardiac pulmonary edema (in pheochromocytoma).It causes to improvement of respiratory failure and decreased intubation in severe asthma attack.in this trial,goal is whether that MgSo4 infusion in decreased hospitalization duration, decreased intubation, decreased dysrhythmia incidence that should be treat in ED, improvement both SaO2 and dyspnea score(verbal quantitative scale) in 6 hours after treatment initiation? this trial is doing randomized single blind clinical trial. pateints with acute cardiac pulmonary edema divided in 2 groups randomizely after that explained about trial and side effect of Mgso4 infusion. one group name is intervention that giving to patient 1 gr Mgso4 in 100 cc normal saline for 20 min, another group name is control that 100 cc normal saline infused for 20 min as placebo. both groups patients received Loop diuretics or thiazides in last month ago. if intervention patients show symptoms of Mgso4 toxicity (eg: patella areflexia or pulmonary depression) or with renal failure, exit this group. Primary outcome measure are MgSo4 infusion in decreased hospitalization duration, decreased intubation, decreased dysrhythmia incidence that should be treat in ED, improvement both SaO2 and dyspnea score(verbal quantitative scale) in 6 hours after treatment initiation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203089235N1**
Registration date: **2012-10-16, 1391/07/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-10-16, 1391/07/25

Registrant information

Name

Seyyed Mahdi Zia Ziabari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1551 7531

Email address

sm-ziabari@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

publicdomain

Expected recruitment start date

2012-06-05, 1391/03/16

Expected recruitment end date

2013-06-06, 1392/03/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Determination of mgso4 infusion effect for treatment of patient with acute pulmonary edema arrived rasol and sina hospital from khordad 1391 to khordad 1392

Public title
Determination of mgso4 infusion effect for treatment of patient with acute pulmonary edema arrived rasol and sina hospital from khordad 1391 to khordad 1392

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:patient with acute pulmonary edema
Exclusion criteria:presence of mgso4 side effects

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran university medical scince

Street address
Tehran porsina street north aspect of tehran university

City
Tehran

Postal code
1417613151

Approval date
2012-06-05, 1391/03/16

Ethics committee reference number
130/272/91/ذ

Health conditions studied

1

Description of health condition studied
Acute pulmonary edema

ICD-10 code
150.1

ICD-10 code description
with mention of heart disease NOS or heart failure

Primary outcomes

1

Description
hospitalization duration

Timepoint
for 6 hours after trial initation

Method of measurement
Compare of hospitalization duration in two groups

2

Description
dysrhythmia incidence that should be treat in ED

Timepoint
for 6 hours after trial initation

Method of measurement
Compare of demand to intubation in two groups

3

Description
necessary for intubation

Timepoint
for 6 hours after trial initation

Method of measurement
Compare of incidence of dysrhytmia that demand treatment in two groups

4

Description
improvement both SaO2 and dyspnea score(verbal quantitative scale) in 6 hours after treatment initiation

Timepoint
for 6 hours after trial initation

Method of measurement
Compare of Sao2 improvement more than 94% and dyspnea score (by verbal quantitative scale pathway) for 6 hours after treatment initiation in two groups

Secondary outcomes

1

Description
Decrease respiratory rate under 8/min

Timepoint
for 6 hours from tretment initation

Method of measurement

Account respiratory rate in 1 minute

2

Description
Diminish of deep tendon reflex
Timepoint
for 6 hours after treatment initation
Method of measurement
Monitoring of deep tendon reflex

Intervention groups

1

Description
In intervention group start treatment by o2 until o2Sat of patient >94% (minimum by 4 lit/min o2),plus Amp lasix 1 mgr/kg and Amp nitroglycerin 5 mic gr/min started and titrated 5 mic gr/min if patients blood pressure permitted, and Amp morphine sulfate 0.05 mgr/kg for attention of patient blood pressure (preferly systolic blood pressure> 90 mmhg).these treatment are basic treatment of acute pulmonary edema. in addition to in intervention group gives 1 gr Mgso4 in 100 cc normal saline for 20 min.
Category
Treatment - Drugs

2

Description
In control group start treatment by o2 until o2Sat of patient >94% (minimum by 4 lit/min o2),Amp lasix 1 mgr/kg and Amp nitroglycerin by 5 mi cgr/min started and titrated 5 mi cgr/min if patients blood pressure permitted, and Amp morphine sulfate 0.05 mgr/kg for attention of patient blood pressure (preferly systolic blood pressure> 90 mm hg).these treatment are basic treatment of acute pulmonary edema.but in control group we administrate basic treatment of acute pulmonary edema and not infused Mgso4. as we administrate 100 cc normal saline in 20 min for placebo instead Mgso4
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul and Sina hospital
Full name of responsible person
Seyyed Mahdi Zia Ziabari M.D
Street address
City
Rssht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran university medical scince
Full name of responsible person
Dr. Akbar Fotohi
Street address
Teran Rasol hospital
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 medical scince
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
Tehran university medical scince
Full name of responsible person
Dr.Seyyed Mahdi Zia Ziabari M.D
Position
Emergency medicine assistant
Other areas of specialty/work
Street address
Satarkhan shahrara rasoul hospital
City
Tehran
Postal code
Phone
+98 21 6652 5327
Fax
Email
smzz592000@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran university medical scince
Full name of responsible person
Dr.Peyman Hafezi Moghadam

Position
Professor assistant of emergency medicine
Other areas of specialty/work
Street address
Satarkhan shahrara rasoul hospital
City
Tehran
Postal code
Phone
+98 21 6652 5327
Fax
Email
hafezimoghadam@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran university medical scince
Full name of responsible person
Dr.Seyyed Mahdi Zia Ziabari M.D
Position
Emergency medicine assistant
Other areas of specialty/work
Street address
Tehran-shahrara-rasoul hospital
City
Tehran
Postal code
Phone
+98 21 6652 5327
Fax
Email
smzz592000@yahoo.com
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
Analytic Code
empty
Data Dictionary
empty