Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of nebulized magnesium sulfate with placebo in the management of patients with moderate to severe acute asthma attack presented to the emergency department

Protocol summary

Summary

The aim of this study is to evaluate the efficacy of nebulized magnesium sulfate in management of moderate to severe asthma attack.In this double blind ,placebo controlled , multicenter randomized clinical trial 50 patients with moderate to severe asthma attack presenting to emergency department of Rasoul Akram, Sina and Firouzgar hospital in Tehran will be included. Patients with renal or liver insuficiency, heart failure and intubated patients will be excluded. Patients are randomly assigned to two group (case and control) each one containing 25 patients. patients in case group will receive 50 mg oral prednisolone, 2.5 mg nebulized salbutamol, 0.5 mg nebulized atrovent and 500 mg nebulized magnesium sulfate each 20 minutes up to 1 hour. Patients in control group will be the same as case group but instead of magnesium sulfate will receive normal saline as placebo. In both groups predicted expirator flow rate will be assessed with peak flowmetere at the beginning and each 20 minutes up to 1 hour. hospital admission , subjective dyspnea scale changes and side effects of treatment also will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022412588N1**
Registration date: **2013-03-18, 1391/12/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-03-18, 1391/12/28

Registrant information

Name

Seyed hossein Shaker

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6651 8098

Email address

sh-shaker@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

vise-challenger of research , Tehran University of Medical Sciences .

Expected recruitment start date

2013-03-05, 1391/12/15

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of nebulized magnesium sulfate with placebo in the management of patients with moderate to severe acute asthma attack presented to the emergency department

Public title

Effect of nebulized magnesium sulfate in management of acute asthma attack

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : patients with moderate to sever acute asthma attack presenting to emergency department
Exclusion criteria : age less than 16 and more than 75 ,liver failure, renal failure, heart failure, fever, intubation and who are dissatisfied for trial.

Age
From **16 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Tehran University of Medical Sciences (TUMS)

Street address
Central building of University, Ghods Ave., Keshavarz Boulevard

City
Tehran

Postal code

Approval date
2011-09-07, 1390/06/16

Ethics committee reference number
210/10240/90/د

Health conditions studied

1

Description of health condition studied
asthma

ICD-10 code
J46

ICD-10 code description
Acute severe asthma

Primary outcomes

1

Description
Predicted Peak Expiratory Flow Rate

Timepoint
Before intervention, at 20, 40, 60 minutes after intervention

Method of measurement
Peak Flowmeter

2

Description
Hospitalization

Timepoint
After 1 hour of intervention

Method of measurement
Data will be recorded by blinded emergency resident

Secondary outcomes

1

Description
Severity of dyspnea

Timepoint
Before intervention, and at 20, 40, 60 minutes after intervention

Method of measurement
Subjective dyspnea scale between 0 and 10

2

Description
Complicatins

Timepoint
After 1 hour of intervention

Method of measurement
Data will be recorded by blinded emergency resident

Intervention groups

1

Description
In addition of standard treatment of asthma (50 mg oral prednisolone, 2.5 mg nebulized salbutamol, 0.5 mg nebulized atrovent), case group will receive 500 mg of nebulized magnesium sulfate (1cc of sulfate 50%) each 20 minutes up to 1 hour.

Category
Treatment - Drugs

2

Description
standard treatment of asthma (50 mg oral prednisolone, 2.5 mg nebulized salbutamol, 0.5 mg nebulized atrovent) but instead of nebulized magnesium sulfate will bli receive 1cc of nebulized normal saline each 20 minutes

up to 1 hour as placebo.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Rasul Akram Hospital

Full name of responsible person
Pegah Akhavan Azari

Street address
Hazrat Rasoul Akram Hospital, Niayesh Ave., Shahid Chamran Highway.

City
Tehran

2

Recruitment center

Name of recruitment center
Firuzgar Hospital

Full name of responsible person
Pegah Akhavan Azari

Street address
Firuzgar Hospital, Behafarin Ave., Valiasr Square

City
Tehran

3

Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person
Pegah Akhavan Azari

Street address
Sina Hospital, Hassan abad Square, Emam Khomeini Ave.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vise-Challenger of research of Tehran University of Medical Sciences

Full name of responsible person
Akbar Fotouhi

Street address
Central Building of University, Ghods Ave., Keshavarz Boulevard

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Vise-Challenger of research of Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Seyed Hossein Shaker

Position
Assistant Professor

Other areas of specialty/work

Street address
Rasul Akram Hospital, Niayesh Ave., Shahid Chamran Highway

City
Tehran

Postal code

Phone
+98 21 6651 5000

Fax

Email
sh-shaker@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Seyed Hossein Shaker

Position
Assistant Professor

Other areas of specialty/work

Street address
Hazrat Rasul Akram Hospital, Niayesh Ave, Shahid Chamran Highway

City
Tehran

Postal code

Phone
+98 21 6651 5000

Fax

Email
sh-shaker@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Pegah Akhavan Azari

Position
Emergency Medicine Resident

Other areas of specialty/work

Street address
Hazrat Rasul Hospital, Niayesh Ave, Shahid Chamran Highway

City
Tehran

Postal code

Phone
+98 21 6651 5000

Fax

Email
pegahakhavan@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