

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 insufficiency, heart failure and intubated patients will be excluded. Patients are randomly assigned to two groups (case and control) each one containing 25 patients. Patients in the 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 the control group will be the same as the 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 flowmeter 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 severe 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

210/10240/90/3

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

Complications

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 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

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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