Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of clinical and Spirometric response between nebulized salbutamol _ magnesium sulfate and nebulized salbutamol alone in acute asthma attack

Protocol summary

Summary

Objective: To investigate the effect of magnesium sulfate in acute asthma nebulizer. Inclusion criteria: having a history of asthma, a minimum 18 years and maximum 65 years. Exclusion criteria: COPD; kidney disease; CHF; pneumonitis; respiratory disease have underlying. This clinical trial study was conducted on 146 patients in the intervention and control groups. 0,20,40,60 minutes have been spirometry and FEV1 and PEFR values are checked and recorded. Immediately after spirometry, nebulize salbutamol at a dose of 2 / 5cc with magnesium sulfate 1/5 cc (20g / 100cc) in the intervention group and nebulize salbutamol 2 / 5cc with 1 / 5cc in the control group received normal saline. The main outcome variables in both groups were evaluated and compared with the peak flow meter parameters.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111015446N8**
Registration date: **2015-11-27, 1394/09/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-11-27, 1394/09/06

Registrant information

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Hassan Motamed
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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-03-22, 1393/01/02

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical and Spirometric response between nebulized salbutamol _ magnesium sulfate and nebulized salbutamol alone in acute asthma attack

Public title

Comparison of clinical and Spirometric response between nebulized salbutamol _ magnesium sulfate and nebulized salbutamol alone in acute asthma attack

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with clinical and para-clinical asthma has been confirmed; age 18 years and maximum 65 years. Exclusion criteria: COPD; CHF; pneumonitis, pulmonary disease lightweight, pregnancy, lactation, is febrile, receiving salbutamol 6 hours before the visit.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **146**

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

Ethics Committee of Ahvaz University of Medical Sciences

Street address

Research Assistant, Next to central Building, Ahvaz Jundishapur University of Medical Sciences, University town, Ahvaz

City

Ahvaz

Postal code

6135715794

Approval date

2014-03-08, 1392/12/17

Ethics committee reference number

u-92231

Health conditions studied

1

Description of health condition studied

Acute attack asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Clinical state

Timepoint

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

Method of measurement

Base on alert status,talking,wizing,use of respiratory mu

2

Description

Forced Expiratory Volum in First Secend (FEV1)

Timepoint

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

Method of measurement

Mililiter with use of Peak Flow Meter

3

Description

Peak Expiratory Flow Rate(PEFR)

Timepoint

Before intervention,20,40,60 minutes after intervention

Method of measurement

Mililiter with use of Peak Flow Meter

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before intervention,20,40,60 minutes after intervention

Method of measurement

mm Hg

2

Description

Pulse Rate

Timepoint

Before intervention,20,40,60 minutes after intervention

Method of measurement

Rate/Minutes

3

Description

Respiratory Rate

Timepoint

Before intervention,20,40,60 minutes after intervention

Method of measurement

Rate/Minutes

4

Description

Saturation of arterial blood oxygen (SO2 %)

Timepoint

Before intervention,20,40,60 minutes after intervention

Method of measurement

with Pulse Oximetry

Intervention groups

1

Description
The intervention group were recorded at 0, 20, 40, 60 spirometric values of FEV1 and PEFR were measured and recorded. For each patient to record the values of FEV1 and PEFR, 3 times a spirometry performed and is considered the highest number. Immediately after spirometry, nebulize salbutamol dose (2.5 mg), as well as magnesium sulfate 20 g / 100CC) 1.5 CC) done.
Category
Treatment - Drugs

2

Description
The control group were recorded at 0, 20, 40, 60 spirometric values of FEV1 and PEFR were measured and recorded. For each patient to record the values of FEV1 and PEFR, 3 times a spirometry performed and is considered the highest number. Immediately after spirometry, nebulize salbutamol 2 / 5CC (2.5 mg), with 1.5 CC of saline in the control group will receive.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Golestan Hospital
Full name of responsible person
DR.Hasan Motamed
Street address
Golestan,Ahvaz Golestan Hospital
City
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2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
DR.Hasan Motamed
Street address
Imam Khomeini Hospital , 24 metri street, Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chanceller for research,Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
DR.Nader Saki
Street address
Research Assistant,Next to center Building,
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chanceller for research,Ahvaz Jundishapur 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
Emergency Medicine Assistant Professor
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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