

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of salbutamol and magnesium sulfate nebulizer compared with salbutamol and normal saline nebulizer in the treatment of acute asthma attack

Protocol summary

Summary

Diagnostic criteria of asthma is according to GINA with respect to history - clinical examination and, if necessary, respiratory function tests and moderate to severe asthma criteria is according to GINA criteria. Before, 30,60 and 90 minutes after treatment, respiratory index score and PEFr will be measured by peak flow meter (Germany, model REF HS755EU) for each patient and age and gender of the patients will be recorded. Then salbutamol+magnesium sulfate nebulizer and salbutamol+normal saline nebulizer will be done for each patient with a Jet nebulizer from Omeron company at 0, 30,60 and 90 minutes. Magnesium sulfate 7.5% (isotonic) and 15mg/kg Salbutamol will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110024396N3**
Registration date: **2012-04-16, 1391/01/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-16, 1391/01/28

Registrant information

Name

Iraj Mohammadzadeh

Name of organization / entity

Non-communicable pediatric diseases research center

Country

Iran (Islamic Republic of)

Phone

+98 11 1324 2151

Email address

i.mohammadzadeh@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-09-21, 1391/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of salbutamol and magnesium sulfate nebulizer compared with salbutamol and normal saline nebulizer in the treatment of acute asthma attack

Public title

Effect of salbutamol and magnesium sulfate nebulizer compared with salbutamol and normal saline nebulizer in the treatment of acute asthma attack

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children aged 5-14 years, suffering from moderate or severe asthma with asthma attack
Exclusion criteria: History of steroid therapy, theophylline, Atrovent in the past three days; a history of chronic diseases such as Bronchopulmonary dysplasia, cystic fibrosis and known allergy to magnesium sulphate and salbutamol and the inability to perform peak flow meter

Age

From **5 years** old to **14 years** old

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)

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 Babol university of medical sciences

Street address

Babol university of medical sciences

City

Babol

Postal code

Approval date

2011-01-21, 1389/11/01

Ethics committee reference number

4618 /30/ پ ٲ

Health conditions studied

1

Description of health condition studied

Pediatric asthma

ICD-10 code

J45.9

ICD-10 code description

Asthma, unspecified

Primary outcomes

1

Description

Increase of PEFr (Peak Expiratory Flow Rate)

Timepoint

0,30,60 and 90 minutes after entrance

Method of measurement

With peak flow meter

Secondary outcomes

1

Description

Pulmonary index

Timepoint

At 0, 30, 60 , 90th minute

Method of measurement

By using Pulmonary index table

Intervention groups

1

Description

At first the asthma is diagnosed according to GINA criteria and history, clinical examination and if possible, respiratory function tests and will be categorized as moderate to severe asthma. before treatment and 30, 60 and 90 minutes after that, respiratory index score and PEFr will be measured by a peak flow meter for each patient and age and gender will be recorded. Then salbutamol+magnesium sulfate nebulizer at 0,30,60,90 minutes will be nebulized. Magnesium sulfate 7.5% (isotonic) and 0.15 mg/kg salbutamol will be used

Category

Treatment - Drugs

2

Description

At first the asthma is diagnosed according to GINA criteria and history, clinical examination and if possible, respiratory function tests and will be categorized as moderate to severe asthma. before treatment and 30, 60 and 90 minutes after that, respiratory index score and PEFr will be measured by a peak flow meter for each patient and age and gender will be recorded. Then salbutamol+normal saline nebulizer at 0,30,60,90 minutes will be nebulized. Magnesium sulfate 7.5% (isotonic) and 0.15 mg/kg salbutamol will be used

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkola Children's Hospital

Full name of responsible person

Iraj Mohammadzadeh, MD

Street address

Babol-Amirkola- Amirkola Children's Hospital

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Babol University of Medical Sciences

Full name of responsible person

Amrollah Mostafazadeh

Street address

Babol university of medical sciences

City

Babol

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, Babol 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

Non-Communicable Pediatric Diseases Research Center

Full name of responsible person

Iraj Mohammadzadeh, MD

Position

Clinical asthma and immunology superspecialist

Other areas of specialty/work

Street address

Babol-Amirkola- Amirkola Children's Hospital

City

Babol

Postal code

Phone

+98 911 111 2228

Fax

+98 11 1324 6963

Email

i.mohammadzadeh@mubabol.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Non-Communicable Pediatric Diseases Research Center

Full name of responsible person

Iraj Mohammadzadeh

Position

Associate professor

Other areas of specialty/work

Street address

Babol-Amirkola- Amirkola Children's Hospital

City

Babol

Postal code

Phone

+98 911 111 2228

Fax

+98 11 1324 6963

Email

i.mohammadzadeh@mubabol.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Science

Full name of responsible person

Mohsen Mohammadi

Position

MD, Resident of Pediatrics

Other areas of specialty/work

Street address

Babol-Amirkola- Amirkola Children's Hospital

City

Babol

Postal code

Phone

+98 911 126 3074

Fax

+98 11 1324 6963

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

Analytic Code

empty

Data Dictionary

empty