Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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 ژ

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 salbotamol+magnesium sulfate nebulizer at 0,30,60,90 minutes will be nebulized. Magnesium sulfate 7.5% (isotonic) and 0.15 mg/kg salbotamol 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 salbotamol+normal saline nebulizer at 0,30,60,90 minutes will be nebulized. Magnesium sulfate 7.5% (isotonic) and 0.15 mg/kg salbotamol 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

Babol

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
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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 asthm and immunology superspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Non-Communicable Pediatric Diseases Research Center
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Iraj Mohammadzadeh
Position
Associate professor
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Science
Full name of responsible person
Mohsen Mohammadi
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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