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

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
None

Sample size
Target sample size: 40
Randomization (investigator's opinion)
Randomized

Randomization description
Blinded (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/

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, and 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
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
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

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Babol-Amirkola- Amirkola Children's Hospital

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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

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i.mohammadzadeh@mubabol.ac.ir

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

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

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