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  
Double blinded

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/

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  

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
empty
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
Street address
Babol-Amirkola- Amirkola Children's Hospital
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Postal code
empty
Phone
+98 911 126 3074
Fax
+98 11 1324 6963
Email
i.mohammadzadeh@mubabol.ac.ir
Web page address
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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
empty
Street address
Babol-Amirkola- Amirkola Children's Hospital
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Fax
+98 11 1324 6963
Email
i.mohammadzadeh@mubabol.ac.ir
Web page address
empty

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