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Magnesium sulfate in the treatment of acute asthma

Submission date	Recruitment status	[_] Prospectively registered
30/08/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/01/2017	Respiratory	

Plain English summary of protocol

Background and study aims
Asthma is a long-term condition which affects the airways. It can affect people of any age, however in most cases it starts in childhood. When a person is suffering from asthma, the airways are extremely sensitive (hyperresponsive) to both natural chemicals the body produces and irritants outside the body, such as dust or pollen. Common into contact with these substances can cause an asthma attack (also known as an exacerbation), which involves feelings of tightness in the chest as the airways become inflamed, causing coughing, wheezing, chest tightness and difficulty breathing. Severe acute (sudden) asthma exacerbation is a medical emergency that must be quickly diagnosed and treated. In many cases, a drug called Salbutamol is given, which works by opening up the narrowed airways. Magnesium sulfate has been shown to be an effective treatment for acute (sudden) asthma exacerbations, however it is not known whether it is beneficial in the long-term. The aim of this study is to find out whether inhaling magnesium sulphate is an effective treatment for asthma exacerbations.

Who can participate?
Asthmatic children aged between 5 and 14 who are having a moderate to severe exacerbation.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive salbutamol solution plus isotonic magnesium sulfate through a nebulizer (a device which delivers the medication as a fine spray so it can be inhaled). Participants in the second group receive salbutamol solution alone through a nebulizer. For both groups, participants receive three doses spaced 20 minutes apart. Each dosing takes around 5-10 minutes to deliver. Before and 20 minutes after receiving each dose, participants undergo a number of breathing tests to find out how well their lungs are working.

What are the possible benefits and risks of participating?
Children who receive the salbutamol plus isotonic magnesium sulfate may benefit from an improvement to their asthma symptoms. There are no notable risks involved with participating.

Where is the study run from?
Alexandria University Faculty of Medicine (Egypt)

When is the study starting and how long is it expected to run for?
April 2015 to February 2016

Who is funding the study?
Alexandria University (Egypt)

Who is the main contact?
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Additional identifiers

Protocol serial number
01028032

Study information

Scientific Title
Inhaled magnesium sulfate in the treatment of acute asthma exacerbation in children

Study objectives
The aim of this study is to assess the efficacy of adding inhaled magnesium sulfate to β-agonist in the management of acute asthma exacerbations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of Alexandria School of Medicine, 25/03/2015, ref: 01028032

Study design
Prospective double-blind placebo controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute asthma

Interventions
The children included in the study are divided randomly in two groups;

Group A: Participants receive inhaled salbutamol solution (Farcolin respirator solution, PHARCO, Alexandria, Egypt), (0.15ml/kg) plus isotonic magnesium sulfate (magnesium sulfate, EIPICO, Alexandria, Egypt (2 ml) in a nebulizer chamber

Group B: Participants receive inhaled salbutamol solution (Farcolin respirator solution, PHARCO, Alexandria, Egypt), (0.15ml/kg), diluted with placebo (normal saline, Haidyl, Alexandria, Egypt) 2ml in a nebulizer chamber.

Participants in both groups receive the inhaled solution using a nebuliser three times, taking approximately 5-10 minutes per dose. Inhalation is repeated for three doses. Each child is evaluated at baseline, and then every 20 minutes after each nebulisation

Intervention Type
Drug

Primary outcome(s)
1. Asthma severity is measured using the Pediatric Asthma Severity Score (PASS) at baseline, 20, 40 and 60 minutes post-nebulisation
2. Oxygen saturation is measured using pulse oximetry at baseline, 20, 40 and 60 minutes post-nebulisation

3. Lung function is assessed through measuring peak expiratory flow rate (PEFR) at baseline, 20, 40 and 60 minutes post-nebulisation

Key secondary outcome(s))
No secondary outcome measures

Completion date
15/02/2016

Eligibility

Key inclusion criteria
1. Children diagnosed as asthmatic according to The Global Initiative for Asthma (GINA) guidelines
2. Aged 5-14 years old
3. Capable of measuring PEFR
4. Presenting with moderate to severe acute exacerbation according to pediatric asthma severity score and PEFR

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
14 years

Sex
All

Key exclusion criteria
1. Severely ill patients requiring immediate hospital care
2. Any evidence of respiratory tract infection or suppurative lung diseases
3. Any history of cardiac, renal or hepatic dysfunction
4. Use of short acting bronchodilator within 8 hours or long acting within 24 hours
5. Use of systemic steroids within 72 hours
6. Children known to have immunodeficiency
7. History of previous asthmatic attacks managed by ICU admissions

Date of first enrolment
01/05/2015

Date of final enrolment

15/12/2015

Locations

Countries of recruitment
Egypt

Study participating centre
Alexandria University Faculty of Medicine
Children's Hospital at Shatebi
Al Azaritah WA Ash Shatebi
Qesm Bab Sharqi
Alexandria
Egypt
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Sponsor information

Organisation
Alexandria University

ROR
https://ror.org/00mzz1w90

Funder(s)

Funder type
University/education

Funder Name
Alexandria University

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		02/09/2016	27/09/2016	No	No