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A randomised, placebo-controlled study of nebulised magnesium in acute severe asthma in children

Submission date
05/11/2007

Recruitment status
No longer recruiting

Registration date
15/11/2007

Overall study status
Completed

Last Edited
24/07/2019

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Asthma is a common long-term condition that can cause coughing, wheezing, chest tightness and breathlessness. There is uncertainty in the management of acute asthma, with major differences between the management of children and adults. Adults are given magnesium intravenously (into a vein) early in the treatment of an acute asthma attack, but this is not recommended in children. Although magnesium is very safe when given intravenously, there is a need to monitor blood levels. A recent study in adults has demonstrated a good effect for magnesium given via a nebuliser (a machine that delivers medication by turning it into a mist to be inhaled through a face mask or mouthpiece). The aim of this study is to determine whether nebulised magnesium is useful in the treatment of acute asthma in childhood. Currently, the next step in the guidelines would be to commence intravenous treatment with medication to dilate (open up) the airways. If children respond to nebulised magnesium at this stage they may not need to go on to have a canula (needle) placed in the vein for more intensive treatment.

Who can participate?
Children aged 2-16 with severe acute asthma

What does the study involve?
When the child attends either a hospital emergency department or an emergency paediatric unit, if they do not respond to the standard treatment in the first 20 minutes, then they are randomly allocated to receive nebulised salbutamol and ipratropium bromide mixed with either magnesium sulphate or saline (dummy drug) on three occasions at 20-minute intervals. They are closely monitored over the following four hours.

What are the possible benefits and risks of participating?
There are few side effects from magnesium, none described for inhaled magnesium, but these will be monitored by an independent committee.

Where is the study run from?
University Hospital of Wales (UK)

When is the study starting and how long is it expected to run for?
December 2007 to November 2010

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Colin Powell
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 05/503/10

Study information

Scientific Title
A randomised, placebo-controlled study of nebulised magnesium in acute severe asthma in children

Acronym
MAGNETIC

Study objectives
Does nebulised magnesium used as an adjunct to nebulised salbutamol and ipratropium bromide for one hour in children with severe asthma result in a clinical improvement when compared to nebulsied salbutamol, ipratropium bromide and placebo?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0550310
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/51218/PRO-05-503-10.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Research Ethics Committee, 18/02/2008, ref: 07/H1010/101

Study design
Multicentre randomised placebo-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe exacerbation of asthma

Interventions
Children aged 2 - 5 years will be randomised to receive nebulised salbutamol 2.5 mg and ipratropium bromide 0.25 mg mixed with either 2.5 ml of isotonic magnesium sulphate (250 mmol/L, tonicity 289 mOsm; 151 mg per dose) or 2.5 ml of isotonic saline on three occasions at twenty-minute intervals. Children 6 years and over will receive 5 mg of nebulised salbutamol.

Total duration of follow-up is one month.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Magnesium, salbutamol, ipratropium bromide

Primary outcome(s)
The Yung Asthma Severity Score (ASS) after 60 minutes of treatment

Key secondary outcome(s))
Clinical (during hospitalisation):
1. Stepping down of treatment at one hour i.e. changed to having hourly treatment after the initial three, twenty-minute nebulisers
2. Number and frequency of additional salbutamol
3. Length of stay in hospital
4. Requirement for intravenous bronchodilator treatment
5. Intubation and/or admission to a Paediatric Intensive Care Unit (PICU)

Patient outcomes at follow-up (1 month):
1. Paediatric Quality of Life Inventory (PedsQL™) asthma module parental report for all children and self-completion if aged over 5 years, European Quality of Life questionnaire (EQ-5D)
2. Time off school/nursery
3. Health care resource usage (e.g. General Practitioner [GP] visits, additional prescribing)

Parent outcomes at follow-up (1 month):
1. Time off work (related to childs illness)

Completion date
25/10/2011

Eligibility

Key inclusion criteria
For children 6 years and older severe asthma is based on at least one of the following criteria being met:
1. Oxygen saturations less than 92% while breathing room air
2. Too breathless to talk
3. Heart rate greater than 120/min
4. Respiratory rate greater than 30/min
5. Use of accessory neck muscles

For children aged 2 - 5 years of age, severe asthma is based on at least one of the following criteria being met:
1. Oxygen saturations less than 92% while breathing room air
2. Too breathless to talk
3. Heart rate greater than 130/min
4. Respiratory rate greater than 50/min
5. Use of accessory neck muscles

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Sex
All

Key exclusion criteria
1. Coexisting respiratory disease such as cystic fibrosis, chronic lung disease of prematurity
2. Severe renal disease
3. Severe liver disease

4. Known to be pregnant
5. Known to have had a reaction to magnesium previously
6. Parents who are unable to give informed consent
7. Previously randomised into MAGNETIC trial
8. Patients who present with life threatening symptoms
9. Previously involved with a trial of a medicinal product in the three months preceding screening

Date of first enrolment
01/12/2007

Date of final enrolment
30/11/2010

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
University Hospital of Wales
Cardiff
United Kingdom
CF14 4XW

Sponsor information

Organisation
Cardiff University (UK)

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2013		Yes	No
Results article	results	01/10/2013		Yes	No
Results article	results	23/12/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes