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Efficacy of Metered Dose Inhaler (MDI) with attached Bottle spacer for bronchodilator therapy in infants and young children with acute lower airways obstruction (South Africa)

Submission date
27/07/2004

Recruitment status
No longer recruiting

Registration date
28/07/2004

Overall study status
Completed

Last Edited
11/10/2007

Condition category
Respiratory

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
WHO/CAH ID 02002

Study information

Scientific Title

Study objectives
To compare the response to bronchodilator administered via a Metered Dose Inhaler (MDI) with bottle spacer compared to a MDI with conventional spacer in young children presenting to a health care facility with acute lower airways obstruction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. University of Cape Town Research and Ethics Committee, University of Cape Town
2. World Health Organization (WHO) Ethical Review Committee

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute lower airways obstruction

Interventions
This is an equivalence study. Equivalence will be regarded as not more than an absolute 10% increase in hospitalisation with the bottle spacer. Assuming that hospitalisation with the conventional spacer will occur in 20% of children and that the spacers are equally effective, 198 children will be required in each group (total sample of 396 children) to demonstrate that hospitalisation with the bottle spacer is not more than 10% higher, with 80% power and a one-tailed a of 0.0505 i.e. given the above assumptions, the upper 90% confidence limit for a difference favouring the conventional spacer will be less than 10%.

Three different delivery systems will be compared:
1. Conventional spacer with MDI - a small volume (150 ml) valved spacer with an attached mask for children less than 3 years, and a mouthpiece for those 3 - 5 years
2. Modified 500 ml plastic bottle with MDI with attached mask for children less than 3 years
3. Jet nebuliser with attached mask or mouthpiece depending upon child's age

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The need for hospitalisation: this outcome has been chosen as this is clinically important and can be reliably measured. Differences between the two treatment groups for this primary outcome

as a result of bias should be minimised by use of random allocation of treatment group with adequate allocation concealment and adequate blinding of the investigators deciding on hospitalisation.

Key secondary outcome(s))
1. Change in clinical score, measured as the difference between the clinical score at presentation to the clinical score recorded after the final bronchodilator treatment prior to discharge or hospitalisation
2. Change in oximetry, measured as the difference between oximetry recorded at presentation the room air to that recorded after the final bronchodilator treatment prior to discharge or hospitalisation
3. Number of bronchodilator treatments required prior to discharge (if not hospitalised). A bronchodilator treatment will be regarded as 5 puffs of salbutamol or a nebulisation
4. Need for systemic corticosteroids. Systemic steroids will be indicated for children with recurrent wheeze who require hospitalisation or who have required two or more bronchodilator treatments

Completion date
01/11/2005

Eligibility

Key inclusion criteria
1. Age 3 months to 5 years
2. Able to use MDI - spacer as assessed by the researcher administering inhaled treatment
3. Acute episode of lower airway obstruction (wheezing or hyperinflation)
4. Informed consent of parent/guardian

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 months

Upper age limit
5 years

Sex
All

Key exclusion criteria
1. Use of bronchodilator within the preceeding 4 hours
2. Known underlying cardiac or chronic pulmonary disease (other than asthma)
3. Presence of stridor or daily treatment with oral corticosteroids for more than 2 days prior

Date of first enrolment
01/04/2003

Date of final enrolment
01/11/2005

Locations

Countries of recruitment
South Africa

Switzerland

Study participating centre
World Health Organization
Geneva -27
Switzerland
CH 1211

Sponsor information

Organisation
The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO) (Switzerland)

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO) (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/02/2007		Yes	No