ISRCTN21515674 https://doi.org/10.1186/ISRCTN21515674

Effectiveness and safety of nebulized budesonide in controlling acute wheezing in under three-year-olds who are unresponsive to fenoterol

Submission date 01/12/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/01/2008	**Overall study status** Completed	
Last Edited 09/10/2015	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Margarete Silva

Contact details
Street Sosuke Shigekiyo, 68 Jardim Patente
Sao Paulo
Brazil
04243-240

Additional identifiers

Protocol serial number
042/2003

Study information

Scientific Title
Effectiveness and safety of nebulized budesonide in controlling acute wheezing in under three-year-olds who are unresponsive to fenoterol

Study objectives
This study aims to compare the efficacy and speed of response to treatment with nebulized budesonide and prednisone on acute wheezing in children under three years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the research ethics committee of the ABC School of Medicine on 5 July 2003 (ref: 042/2003)

Study design
Prospective, randomized, double-blind, placebo-controlled study.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Wheezing in children

Interventions
Budesonide group (30 participants):
Nebulized Budesonide + Placebo (oral) + Fenoterol

Nebulized budesonide (Pulmicort®), 500 µg/dose four times on admission and on the first day. On the second and third day, 500 µg/dose three times per day. On the fourth and fifth day, 500 µg/dose twice per day. Finally, on the sixth and seventh day, 250 µg/dose twice per day. Also, this group took placebo (oral) at the same time and dose as the prednisone group. Nebulized fenoterol, 0.15 mg/kg/dose eight times per day on admission and on the first day. On the second and third day, 0.15mg/kg/dose six times per day. On the fourth and fifth day, 0.10 mg/kg/dose six times per day. Finally, on the sixth and seventh day, 0.10 mg/kg/dose four times per day.

Prednisone roup (30 participants):
Prednisone + Placebo (inhalation) + Fenoterol

Prednisone (Meticorten®), 2 mg/kg/dose once per day on admission, first, second and third day. On the fourth and fifth day, 1.5 mg/kg/dose once per day. Finally, on the sixth and seventh day, 1.0 mg/kg/dose once per day. Nebulized placebo was taken at the same dose and time as the budesonide group. Fenoterol was taken at the same dose and time as written above for the budesonide group.

Control group (15 participants):
Placebo inhalation + Placebo oral + Fenoterol

Placebo inhalation administered at the same time and dose as the budesonide group. Placebo (oral) administered at the same time and dose as the prednisone group and fenoterol was taken at the same dose and time as both budesonide and prednisone groups.

If the clinical situation deteriorated and reached Clinical score >5, two inhalations of fenoterol were given (0.15 mg/Kg/dose, interval 20 min). If the Clinical score did not change, randomization was interrupted and 500 µg of known budesonide was given. If in the following hour the Clinical score reduced and transcutaneous oxygen saturation (TSaO2) >91%, budesonide was maintained at the doses, timepoints and techniques defined in the study protocol. However, if Clinical score >= 7, TSaO2 <90%, arterial oxygen pressure less than 60 mmHg and carbon dioxide >50 mmHg, the study was stopped and considered a failure. Such cases on budesonide were called therapy failure.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Nebulized budesonide and prednisone

Primary outcome(s)
The following were assessed at admission, 20, 40, 60 and 90 min, 2, 4, 6, 12 and 24 hours, in the morning, afternoon, and evening on the first day after discharge from hospital, and then on the 10th and 15th day after discharge:
1. Wood Clinical Score
2. Pulse oximetry (TSaO2)
3. Respiratory frequency
4. Cough intensity
5. Dyspnea
6. Use of emergency bronchodilatory medication

Key secondary outcome(s))
Intensity of stress presented during the treatment, measured by the number of Wood Clinical Score obtained divided per the total patients number.

Completion date
30/10/2006

Eligibility

Key inclusion criteria
1. Children from 1 month to 3 years old
2. Moderate to very severe acute wheezing, defined by a modified Wood clinical score over 3 after three doses of fenoterol at 20 minute intervals

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Child

Lower age limit
1 months

Upper age limit
3 years

Sex
All

Key exclusion criteria
1. Previous use of systemic corticosteroid
2. Inhalation of corticosteroid or topical corticosteroid in the past 10 days
3. Cardiopathy
4. Nephropathy
5. Neuropathy
6. Inadequate nutritional level

Date of first enrolment
30/03/2003

Date of final enrolment
30/10/2006

Locations

Countries of recruitment
Brazil

Study participating centre
Street Sosuke Shigekiyo, 68 Jardim Patente
Sao Paulo
Brazil
04243-240

Sponsor information

Organisation
The University of Medicine of Botucatu (UNESP) (Brazil)

ROR
https://ror.org/00987cb86

Funder(s)

Funder type
Other

Funder Name
Investigator-funded (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration