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
Registration date 14/01/2008	Overall study status Completed	 Statistical analysis plan Results
Last Edited 09/10/2015	Condition category Respiratory	 Individual participant data Record updated in last year

Plain English summary of protocol Not provided at time of registration

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 042/2003

Study information

Scientific Title

Effectiveness and safety of nebulized budesonide in controlling acute wheezing in under threeyear-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

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Intensity of stress presented during the treatment, measured by the number of Wood Clinical Score obtained divided per the total patients number.

Overall study start date

30/03/2003

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

Age group Child

Lower age limit

1 Months

Upper age limit

3 Years

Sex Both

Target number of participants 75

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)

Sponsor details Pediatrics Department District Rubiao Junior Botucatu Sao Paulo Brazil 18618-970

Sponsor type University/education

Website http://www.unesp.br

ROR https://ror.org/00987cb86

Funder(s)

Funder type Other

Funder Name Investigator-funded (Brazil)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary Not provided at time of registration