

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

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|----------------------------------------|---------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>01/12/2007   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>14/01/2008 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                   | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>09/10/2015       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data |
|                                        |                                                   | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Margarete Silva

### Contact details

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## 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 group (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