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# The role of inhaled corticosteroids in children with chronic lung disease of Infancy

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| **Submission date**<br>11/03/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol |
| **Registration date**<br>22/03/2005 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>06/11/2019 | **Condition category**<br>Respiratory | [_] Individual participant data<br>[_] 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

**Clinical Trials Information System (CTIS)**
Nil known

**Protocol serial number**
16027

## Study information

**Scientific Title**
The role of inhaled corticosteroids in children with chronic lung disease of Infancy

## Study objectives
The aim of the study is to study the effect of inhaled steroids on school-aged children with chronic lung disease (CLD). The study hypothesis is that inhaled corticosteroids, Beclomethasone Dipropionate will improve respiratory system resistance after 6 weeks of treatment.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
This study was approved by the conjoint Health Research Ethics Board and Child Health Research Committee at the University of Calgary, Alberta (Canada).

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Chronic lung disease of infancy or bronchopulmonary dysplasia

## Interventions
Children will receive inhaled corticosteroids or placebo for 6 weeks, pulmonary function either forced expiratory volume in 1 second (FEV1) or impulse oscillometry and quality of life will be assessed before and after the intervention.

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Beclomethasone Dipropionate

## Primary outcome(s)
Improvement in respiratory system resistance at 5 Hz frequency using impulse oscillometry after 6 weeks of inhaled corticosteroids in CLD.

## Key secondary outcome(s))
Improvement in quality of life system score using Child Health Questionnaire (CHQ) and FEV1 response to bronchodilators (Salbutamol) after inhaled corticosteroids treatment for 6 weeks in CLD.

## Completion date
31/12/2005

# Eligibility

### Key inclusion criteria
1. 3 - 7 year old children with history of chronic lung disease of infancy
2. Premature birth at 36 weeks gestation or less
3. Clinical and radiological diagnosis of CLD. Patient charts will be reviewed and the x-rays will be reviewed, even if there is no x-ray findings patients will be included if they fulfil the other criteria.
4. Requirement of supplemental oxygen to maintain saturation of 90%, for at least 36 weeks corrected gestation

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
3 years

### Upper age limit
7 years

### Sex
All

### Key exclusion criteria
1. Cardiovascular disease other than patent ductus arteriosus (PDA)
2. Those with severe neurological disease or developmental delay
3. Oxygen requirement for respiratory diagnosis other than CLD, e.g., congenital diaphragmatic hernia and aspiration
4. An inability to perform spirometry or impulse oscillometry (IOS)
5. Noncompliance with therapy
6. Pneumonia

### Date of first enrolment
01/01/2005

### Date of final enrolment
31/12/2005

# Locations

### Countries of recruitment
Canada

Kuwait

**Study participating centre**
**P.O. Box 951**
Ardeyah City
Kuwait
92400

# Sponsor information

**Organisation**
University of Calgary (Canada)

**ROR**
https://ror.org/03yjb2x39

# Funder(s)

**Funder type**
Industry

**Funder Name**
m Pharmaceuticals (Canada) - The pharmaceutical company is providing some funding (in the shape of free drug & placebo and spacers for the inhalers)

# 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? |
|---|---|---|---|---|---|
| Protocol article | Study protocol | 12/04/2005 | | Yes | No |