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

Submission date 11/03/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 22/03/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 06/11/2019	**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

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