

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

Submission date 11/03/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/03/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/11/2019	Condition category 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 Saad Alotaibi

Contact details
P.O. Box 951
Ardeyah City
Kuwait
92400
-
saalotai@hotmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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