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Randomized Trial of Heat Recovery Ventilators (HRVs) for the Prevention of Severe Lower Respiratory Tract Infection (LRTI) in Inuit Infants in Baffin Region, Nunavut, Canada

Submission date
15/08/2005

Registration date
04/11/2005

Last Edited
09/05/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
PERD-089

Study information

Scientific Title
Randomized Trial of Heat Recovery Ventilators (HRVs) for the Prevention of Severe Lower Respiratory Tract Infection (LRTI) in Inuit Infants in Baffin Region, Nunavut, Canada

Study objectives
Heat Recovery Ventilators, by improving indoor air ventilation and indoor air quality will reduce the incidence of severe lower respiratory tract infection requiring admission to hospital in Inuit infants in Baffin Region, Nunavut.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Bronchiolitis, Pneumonia

Interventions
Heat Recovery Ventilator versus placebo Heat Recovery Ventilator

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Admission to hospital for severe lower respiratory tract infection

Secondary outcome measures
Effect of Heat Recovery Ventilators on indoor CO2, Air change rate, respiratory symptoms, occupant comfort, and visits to the nursing station for respiratory illness.

Overall study start date
15/09/2005

Completion date
15/09/2008

Eligibility

Key inclusion criteria
Inuit infants 0-2 years of age living in eligible communities in Baffin Region, Nunavut, Canada

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Years

Upper age limit
2 Years

Sex
Both

Target number of participants
150

Total final enrolment
68

Key exclusion criteria
Children with underlying congenital malformations known to increase the risk of LRTI, including congenital lung malformations and congenital heart disease will be excluded from the study, as well as children with underlying conditions known to increase the risk of LRTI, including cystic fibrosis, severe developmental delay, and immunodeficiency. Houses where it is technically impossible to install the HRV will be excluded from the study. Only households providing informed consent will be allowed to participate in the trial.

Date of first enrolment
15/09/2005

Date of final enrolment
15/09/2008

Locations

Countries of recruitment
Canada

Study participating centre
Children's Hospital of Eastern Ontario
Ottawa
Canada
K1H 8L1

Sponsor information

Organisation
Program of Energy Research and Development (Canada)

Sponsor details
CANMET Energy Technology Centre - Ottawa
Natural Resources Canada
580 Booth Street
13th floor Haanel Drive
Ottawa
Canada
K1A 0E4

Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Program of Energy Research and Development (PERD) PERD-089

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2009	09/05/2019	Yes	No