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

| Statistical analysis plan | |
|---------------------------|--|
| | |
| participant data | |
| | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Thomas Kovesi

Contact details

Children's Hospital of Eastern Ontario 401 Smyth Rd Ottawa Canada K1H 8L1

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 summaryNot 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 |