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A randomised controlled trial of racemic epinephrine versus salbutamol for treatment of respiratory distress in bronchiolitis

Submission date 19/04/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/04/2005	**Overall study status** Completed	
Last Edited 15/02/2008	**Condition category** Respiratory	

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
N/A

Study information

Scientific Title

Study objectives
Aerosolised racemic epinephrine given to hospitalised children under two years of age with bronchiolitis is more effective than aerosolised salbutomol in relieving respiratory distress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The protocol was approved by the Ethics Review Board at both participating institutions.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Racemic epinephrine or salbutamol.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Racemic epinephrine

Primary outcome measure
Wheezing and retractions measured by the Respiratory Distress Assessment Instrument each day during hospitalisation.

Secondary outcome measures

1. Length of stay
2. RSV antigen detection test
3. Feeding pattern
4. Adverse events
5. Parental report of feeding and respiratory status one week after discharge

Overall study start date
01/01/1999

Completion date
31/12/2002

Eligibility

Key inclusion criteria
Children less than two years of age with first episode wheezing.

Participant type(s)
Patient

Age group
Child

Upper age limit
2 Years

Sex
Both

Target number of participants
62

Key exclusion criteria
Children were not eligible for enrollment if they:
1. Had a previous diagnosis of asthma
2. Were critically ill
3. Had chronic pulmonary or cardiac disease

Other exclusion criteria included:
4. Allergy to sodium metabisulfite
5. Presence of tachycardia exceeding 200 beats per minute
6. Use of glucocorticoids
7. Sympathomimetic amines or monoamine oxidase inhibitor therapy

Date of first enrolment
01/01/1999

Date of final enrolment
31/12/2002

Locations

Countries of recruitment
Canada

Study participating centre
5850 University Avenue
Halifax, Nova Scotia
Canada
B3K 6R8

Sponsor information

Organisation
Lung Association of Nova Scotia (Canada)

Sponsor details
17 Alma Crescent
Halifax, Nova Scotia
Canada
B3N 3E6

Sponsor type
Research organisation

Website
http://www.ns.lung.ca/

Funder(s)

Funder type
Research organisation

Funder Name
Lung Association of Nova Scotia (Canada)

Funder Name
IWK Health Center Research Office (Canada)

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	05/05/2005		Yes	No