

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/04/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/02/2008	Condition category Respiratory	<input type="checkbox"/> 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
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 salbutamol 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