

A comparison of nebulized 3% hypertonic saline and epinephrine versus nebulized normal saline and epinephrine in the treatment of acute bronchiolitis

Submission date 01/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/11/2009	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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

BREATH

Study objectives

Bronchiolitis which is the most common lower respiratory tract infection under the age of one. Symptoms can range from mild to severe and include fever, rhinorrhea, cough, and dyspnea.

Compared to nebulized racemic epinephrine in normal saline, patients with acute bronchiolitis in the emergency department treated with nebulized racemic epinephrine in 3% hypertonic saline will have a statistically significant improvement in their Respiratory Assessment Change Score (RACS).

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Bronchiolitis

Interventions

Patients who entered the study were randomized to receive either nebulized epinephrine in hypertonic saline or nebulized epinephrine in normal saline. Each patient had his or her oxygen saturation level, heart rate, respiratory rate and Respiratory Distress Assessment Instrument (RDAI) score measured at baseline and then again at 30, 60, 90 and 120 minutes. The nurses, physicians and study team personnel remained blinded throughout the study. There were no invasive procedures involved.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Nebulized racemic epinephrine in normal saline and nebulized racemic epinephrine in 3% hypertonic saline

Primary outcome measure

The Respiratory Assessment Change Score (RACS) was the primary outcome variable of the study. This score is a clinical scoring system based on the Respiratory Distress Assessment Index (RDAI) and the respiratory rate.

Secondary outcome measures

Oxygen saturation and rate of admission to hospital.

Overall study start date

14/02/2004

Completion date

14/03/2005

Eligibility**Key inclusion criteria**

Infants 6 weeks to 12 months of age with clinical symptoms of a viral respiratory infection (coryza or temperature $\geq 38.0^{\circ}\text{C}$), first episode of wheezing, oxygen saturation $\geq 85\%$ but $\leq 96\%$, and initial Respiratory Distress Assessment Instrument (RDAI) score ≥ 4 .

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Weeks

Upper age limit

12 Months

Sex

Not Specified

Target number of participants

46

Key exclusion criteria

Pre-existing cardiac or pulmonary disease, previous diagnosis of asthma by a physician, any previous use of bronchodilators, severe disease requiring resuscitation room care, inability to administer medication by nebulizer, inability to obtain informed consent secondary to a language barrier, or no phone access for follow-up.

Date of first enrolment

14/02/2004

Date of final enrolment

14/03/2005

Locations**Countries of recruitment**

Canada

Study participating centre

2nd Floor, Rm 7217B

Edmonton, AB

Canada

T6G 2J3

Sponsor information**Organisation**

University of Alberta, Department of Pediatrics (Canada)

Sponsor details

8213 Aberhart Centre 1

11402 University Avenue

Edmonton, AB

Canada

T6G 2J3

Sponsor type

University/education

ROR

<https://ror.org/0160cpw27>

Funder(s)

Funder type

University/education

Funder Name

Department of Pediatrics, University of Alberta, Edmonton, Alberta (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	01/11/2009		Yes	No