

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

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

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

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.

**Key secondary outcome(s)**

Oxygen saturation and rate of admission to hospital.

**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  $\geq 4$ .

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 weeks

**Upper age limit**

12 months

**Sex**

Not Specified

**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)

### 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

### 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?
<a href="#">Results article</a>	results	01/11/2009		Yes	No