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# 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

**Registration date**
13/09/2005

**Last Edited**
16/11/2009

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

## 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 ≥ 38.0°C), first episode of wheezing, oxygen saturation ≥ 85% but ≤ 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
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## 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 |