Canadian Bronchiolitis Epinephrine Steroid Trial

[] Prospectively registered Submission date Recruitment status 26/09/2005 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 26/09/2005 Completed [X] Results [] Individual participant data **Last Edited** Condition category Respiratory 19/05/2025

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

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

MCT-67276

Study information

Scientific Title

A randomised controlled trial of nebulised epinephrine and oral dexamethasone in the treatment of outpatients with bronchiolitis

Acronym

CanBEST

Study objectives

We hypothesise that children presenting to the Emergency Department (ED) with bronchiolitis and who are treated with nebulised epinephrine and/or oral dexamethasone will have fewer hospitalisations and a shorter, less severe illness.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Children's Hospital of Easter Ontario Research Ethics Board gave approval in May 2004.

Study design

Randomized 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

- 1. Oral dexamethasone
- 2. Nebulised epinephrine

Trial details received: 12 Sept 2005

Intervention Type

Drug

Phase

Drug/device/biological/vaccine name(s)

Dexamethasone, epinephrine

Primary outcome measure

Admission to hospital up to 7 days after enrolment

Secondary outcome measures

- 1. Time to discharge
- 2. Length and severity of symptoms
- 3. Change in RDAI
- 4. Economic costs
- 5. Change in oxygen saturation from baseline at times 60, 120, 180 and 240 minutes
- 6. Co-interventions
- 7. Return to be evaluated by health care provider for on-going symptoms related to bronchiolitis
- 8. Adverse events

Overall study start date

01/04/2004

Completion date

31/03/2008

Eligibility

Key inclusion criteria

- 1. Age 6 weeks to 12 months, either sex
- 2. Respiratory distress assessment instrument (RDAI) score of greater than 3 and less than 15
- 3. Diagnosis of bronchiolitis

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Weeks

Upper age limit

12 Months

Sex

Both

Target number of participants

800

Total final enrolment

Key exclusion criteria

- 1. Asthma or any previous episode of wheezing treated with bronchodilators
- 2. Chronic cardiopulmonary disease
- 3. Presence of varicella or recent close contact
- 4. Severe respiratory distress
- 5. Recent treatment with oral or inhaled steroids
- 6. Insurmountable language barrier
- 7. Any child born at less than 37 weeks gestation who is less than 6 weeks corrected age

Date of first enrolment

01/04/2004

Date of final enrolment

31/03/2008

Locations

Countries of recruitment

Canada

Study participating centre Children's Hospital of Eastern Ontario

Ottawa

Canada

K1H 8L1

Sponsor information

Organisation

Children's Hospital of Eastern Ontario (Canada)

Sponsor details

401 Smyth Road Ottawa Canada K1H 8L1 +1 8 737 7600

webmaster@cheo.on.ca

Sponsor type

Hospital/treatment centre

ROR

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-67276)

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	14/05/2009		Yes	No
Results article		16/05/2025	19/05/2025	Yes	No