ISRCTN56745572 https://doi.org/10.1186/ISRCTN56745572

Canadian Bronchiolitis Epinephrine Steroid Trial

Submission date 26/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/09/2005	**Overall study status** Completed	
Last Edited 15/05/2009	**Condition category** Respiratory	

Plain English Summary
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
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 hypothesis
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
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Condition
Bronchiolitis

Interventions
1. Oral dexamethasone
2. Nebulised epinephrine

Trial details received: 12 Sept 2005

Intervention Type
Drug

Phase
Not Applicable

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

Overall study end date
31/03/2008

Eligibility

Participant 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

Participant 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

Recruitment start date
01/04/2004

Recruitment end date
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
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+1 8 737 7600
webmaster@cheo.on.ca

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05nsbhw27

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