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Efficacy of a short course of oral steroids for hospitalised preschool children with viral induced wheeze: a randomised double-blind placebo-controlled trial

Submission date
20/06/2007

Recruitment status
No longer recruiting

Registration date
06/07/2007

Overall study status
Completed

Last Edited
04/02/2009

Condition category
Signs and Symptoms

[_] 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
2004-005124-40

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Asthma UK Funded Project ID 04/039; EudraCT Number: 2004-005124-40

Study information

Scientific Title

Acronym
TWICS (Treatment of Wheeze In Children with Steroids)

Study objectives
The outcome for preschool children (10 months to 60 months) admitted to the hospital with an attack of wheeze triggered by clinical viral infection (preschool viral wheeze) and treated with oral steroids will be no different than those children treated with placebo (primary null hypothesis).

Secondary (null) hypotheses are that compared with oral placebo, treatment of hospitalised children with preschool viral wheeze with oral prednisolone will not:
1. Reduce the severity of respiratory distress at 4, 12, and 24 hours
2. Reduce the total severity of the attack, or the total amount of inhaled bronchodilators
3. Reduce the risk of significant hypoxia or re-admission within 4 weeks

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Fife and Forth Valley Local Research Ethics Committee (MREC ref: 05/S0501/7)
2. Leicestershire Local Research Ethics Committee Two (LREC ref: 05/Q2502/19)
3. Medicines and Healthcare products Regulatory Agency (MHRA) (CTA Number 23071/0001/001-0001)

Study design
Two-centre, three-hospital, randomised, double-blind placebo-controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Preschool wheeze: In children between 1 and 5 years the phenotype of 'asthma' is characterised by transient episodes of wheeze triggered by viral colds with no or few interval symptoms

Interventions
By double-blind, stratified (by centre) randomisation, children will receive either oral corticosteroids for 5 days or placebo along with inhaled bronchodilator therapy (frequency and mode of delivery device decided by the clinician). The dose of the oral corticosteroid, prednisolone will be 20 mg for 2 to 5 year olds and 10 mg for children under age of 2 years.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Prednisolone

Primary outcome measure
Length of stay in hospital, i.e. time from randomisation to discharge from the hospital which will be assessed in two ways: first when the child was felt fit to be discharged by a clinician and second when child was discharged home.

Secondary outcome measures
1. Median symptom score (Preschool Respiratory Assessment Measure [PRAM] score) and parental symptom score (mean 7 day)
2. Total use of inhaled bronchodilators during hospitalisation (from notes) and total for 7 days post discharge (from parental diary and clinical notes)
3. Complications:
3.1. Hypoxia
3.2. Pediatric Intensive Care Unit (PICU) admission
3.3. Readmission within 1 month and withdrawal from the study

Overall study start date
01/01/2005

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Children aged 10 months to 60 months
2. Preceding history of a viral illness with upper respiratory tract symptoms/signs associated with an acute episode of physician diagnosed wheeze (preschool viral wheeze)
3. Who need admission to the hospital

Participant type(s)

Patient

Age group
Child

Lower age limit
10 Months

Upper age limit
60 Months

Sex
Both

Target number of participants
700

Key exclusion criteria
1. Children < 10 months and > 60 months age
2. Fluid resuscitation (more than or equal to 20 ml/kg)
3. Bacterial sepsis (e.g. bacterial pneumonia, meningitis)
4. Cystic fibrosis, bronchiectasis and children with upper respiratory tract structural abnormality
5. Children on home oxygen
6. Diagnosis of immune deficiency
7. History of chronic persistent wheeze with no evidence of a discrete deterioration in association with a clinical cold
8. Active chicken pox
9. Children admitted for social reasons

Date of first enrolment
01/01/2005

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Cell and Molecular Science
London
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Sponsor information

Organisation
Asthma UK

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Sponsor type
Charity

Website
http://asthma.org.uk/

ROR
https://ror.org/03z7xev21

Funder(s)

Funder type
Charity

Funder Name
Asthma UK (Project ID 04/039)

Alternative Name(s)
Asthma UK, Asthma + Lung UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	22/01/2009		Yes	No