

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

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Registration date 06/07/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/02/2009	Condition category Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)
2004-005124-40

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

10 months

Upper age limit

60 months

Sex

All

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**

United Kingdom

England

Study participating centre

Institute of Cell and Molecular Science

London

United Kingdom

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Sponsor information**Organisation**

Asthma UK

ROR

<https://ror.org/03z7xev21>

Funder(s)

Funder type

Charity

Funder Name

Asthma UK (Project ID 04/039)

Alternative Name(s)

asthmalunguk, Asthma UK, Asthma + Lung UK

Funding Body Type

Private sector organisation

Funding Body Subtype

Research institutes and centers

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	22/01/2009		Yes	No