

A randomised controlled trial of oral prednisolone for viral-wheeze in pre-school children with stratification for serum level of Eosinophil Protein X (EPX)

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/03/2007	Condition category Respiratory	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

AM2/01/008

Study information

Scientific Title

Study objectives

This study will test the hypothesis that in preschool children with viral-wheeze, those with atopic pulmonary inflammation will respond to a short course of oral corticosteroids, whereas those with a structurally based vulnerability to wheeze will not.

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Respiratory tract diseases: Asthma

Interventions

Children passing the inclusion criteria will be divided into two groups

a. Those with presenting serum EPX levels of greater than or equal to 25 ug/l

b. Those with EPX levels <25 ug/l.

At the next episode of viral wheeze children in both groups will receive either placebo or a short course of oral prednisolone.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Prednisolone

Primary outcome measure

Outcome will be assessed by parental scoring of respiratory symptoms using a diary card.

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/03/1999

Completion date

28/02/2002

Eligibility

Key inclusion criteria

Children aged between 18 and 48 months of age presenting with viral-wheeze.

Participant type(s)

Patient

Age group

Child

Lower age limit

18 Months

Upper age limit

48 Months

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

No exclusion criteria

Date of first enrolment

01/03/1999

Date of final enrolment

28/02/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Leicester

Leicester

United Kingdom

LE2 7LX

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Asthma National Research and Development Programme (UK)

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?
Abstract results		01/11/2003		No	No