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	Recruitment status No longer recruiting Overall study status	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date		Statistical analysis plan		
23/01/2004	Completed	[X] Results		
Last Edited 13/03/2007	Condition category	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Jonathan Grigg

Contact details

University of Leicester Leicester Royal Infirmary P.O. Box 65 Leicester United Kingdom LE2 7LX +44 (0)116 252 5840 jg33@leicester.ac.uk

Additional identifiers

Protocol serial number 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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s))

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

18 months

Upper age limit

48 months

Sex

Not Specified

Key exclusion criteria

No exclusion criteria

Date of first enrolment

01/03/1999

Date of final enrolment

28/02/2002

Locations

Countries of recruitment

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

NHS Asthma National Research and Development Programme (UK)

Results and Publications

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