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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

Registration date
23/01/2004

Overall study status
Completed

Last Edited
13/03/2007

Condition category
Respiratory

[_] 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

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