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Inhaled Fluticasone in Wheezy Infants

Submission date 07/11/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/11/2005	**Overall study status** Completed	
Last Edited 07/01/2008	**Condition category** Respiratory	

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
N/A

Study information

Scientific Title

Acronym
IFWIN

Study objectives
1. Can the early introduction of inhaled corticosteroids (ICS) prevent the progressive fall in lung function seen in asthmatics?
2. Can early introduction of inhaled corticosteroids in children with asthma modify the natural history of the disease or prevent recurrence of asthma later in life?
3. Does treatment with ICS reduce symptoms in non-asthmatic wheezy children and improve their lung function at age 6 years?
4. Do inhaled corticosteroids improve the quality of life of families with wheezing children?
5. Is continuous treatment with ICS at this dose in young children associated with any local or systemic side effects?

Ethics approval required
Old ethics approval format

Ethics approval(s)
ERP/97/023, 21st April 1997

Study design
A randomized double blind placebo controlled study investigating the effects of early intervention with low dose inhaled corticosteroids (fluticasone propionate) in young children with wheeze

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
Asthma in children

Interventions
Low dose inhaled corticosteroids (fluticasone propionate) versus placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fluticasone propionate

Primary outcome measure
1. Occurrence of asthma at age 5 and 6
2. Lung function at age 5
3. Non-specific bronchial hyper-reactivity at age 5
4. Number of courses and total dose of add-on fluticasone propionate required

Secondary outcome measures
1. Rescue and added asthma medication
2. Number of exacerbations
3. Safety parameters length/height, weight
4. Symptom scores
5. Adrenal function

Overall study start date
01/05/1997

Completion date
31/03/2003

Eligibility

Key inclusion criteria
1. Children aged 6 months to 4 years
2. Two episodes of doctor verified wheeze or one episode continuous for more than 4 weeks

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
4 Years

Sex
Both

Target number of participants
200

Key exclusion criteria

1. Pre-term less than 34 weeks gestation
2. Neonatal lung disease or other lung disease
3. Other chronic disease
4. Children already or previously used an inhaled corticosteroid
5. Children who cannot use the spacer device

Date of first enrolment
01/05/1997

Date of final enrolment
31/03/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North West Lung Research Centre
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Wythenshawe Hospital (UK)

Sponsor details
Andrew Maines
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05vpsdj37

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (UK)

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

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	26/08/2006		Yes	No