ISRCTN04517206 https://doi.org/10.1186/ISRCTN04517206

A multicentre, parallel group, randomised, double blind study to investigate the efficacy of fluticasone 100 mcg metered dose inhaler (MDI) twice a day (bd) versus placebo MDI bd both via Babyhaler® spacer in 1 to 5 year old children with asthma or asthma-like symptoms during a 6 month study period

Submission date
01/02/2005

Recruitment status
No longer recruiting

Registration date
23/03/2005

Overall study status
Completed

Last Edited
15/02/2008

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
FLU 9705

Study information

Scientific Title

Acronym
ASTERISK

Study objectives
To compare the efficacy of fluticasone propionate (FP) with placebo (PBO) using daily record card symptoms (shortness of breath, cough, wheezing, rescue medication use).

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Recurrent respiratory symptoms in children

Interventions
6 months treatment with
1. Fluticasone propionate 50 mcg 2 puffs MDI bd via Babyhaler®, or
2. Placebo 2 puffs MDI bd via Babyhaler® and salbutamol 200 mcg MDI via Babyhaler® as rescue medication

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fluticasone, salbutamol

Primary outcome measure
Symptom score (cough, wheeze, shortness of breath during night and day) as measured by a symptom diary card.

Secondary outcome measures
1. Symptom-free days and nights
2. Use of rescue medication
3. Lung function as measured by the interrupter technique and forced oscillation technique

Overall study start date
01/01/2001

Completion date
31/08/2003

Eligibility

Key inclusion criteria
1. Children aged 1 to 5 years with recurrent respiratory symptoms for which the GP considered prescribing inhaled corticosteroids
2. During the 2-week run-in period, children are eligible if they have symptoms on at least 7 days

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
5 Years

Sex
Not Specified

Target number of participants
96 children (140 were screened, from whom 96 were randomised)

Key exclusion criteria
1. Use of oral steroids within 8 weeks prior to the study
2. Use of inhaled steroids within 4 weeks prior to the study
3. Other respiratory disease
4. Inability of parents to fill in diaries
5. Incapable of using the inhaler device in a proper way
6. Participation in other trials

Date of first enrolment
01/01/2001

Date of final enrolment
31/08/2003

Locations

Countries of recruitment
Netherlands

Study participating centre
Dept. General Practice
Groningen
Netherlands
9713 AV

Sponsor information

Organisation
GlaxoSmithKline (The Netherlands)

Sponsor details
Huis ter Heideweg 62
Zeist
Netherlands
3705 LZ

Sponsor type
Industry

ROR
https://ror.org/05atcw115

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (The Netherlands) (ref: flu9705)

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

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Stichting Astma Bestrijding (The Netherlands) (ref: 2000/006)

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