

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	☐ Prospectively registered ☐ Protocol
Registration date 23/03/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 15/02/2008	Condition category Respiratory	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Thys van der Molen

Contact details
Dept. General Practice
University Medical Center Groningen
A. Deusinglaan 1
Groningen
Netherlands
9713 AV

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 years

Upper age limit

5 years

Sex**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)

ROR

<https://ror.org/05atcw115>

Funder(s)

Funder type

Industry

Funder Name

GlaxoSmithKline (The Netherlands) (ref: flu9705)

Alternative Name(s)

GlaxoSmithKline plc., GSK plc., GlaxoSmithKline 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary