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	Recruitment status	<ul><li>Prospectively registered</li></ul>
01/02/2005	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
23/03/2005	Completed	Results
Last Edited	Condition category	[] Individual participant data
15/02/2008	Respiratory	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

**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