

# Multicentre, parallel group, randomised, double blind study to investigate the efficacy of Montelukast (MK) + Fluticasone (FP) placebo versus Fluticasone + MK-placebo versus MK-placebo + FP-placebo in preschool children with asthma or asthma-like symptoms during a 3 months study period

<b>Submission date</b> 08/06/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 11/09/2009	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

# Study information

## Scientific Title

## Acronym

OBELIKS

## Study objectives

Montelukast mono-therapy is as effective as Fluticasone mono-therapy in pre-school asthmatic children compared to placebo.

## 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

Asthma

## Interventions

Patients are receiving 4 mg of Montelukast as a chewable tablet or Fluticasone propionate 50 mcg 2 puffs metered dose inhaler (MDI) twice a day via babyhaler each with a matching placebo or only placebo for three months.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Montelukast and Fluticasone propionate

## Primary outcome(s)

Difference in average symptom scores and symptom free days and nights during daily record periods between the three treatments in the 3 subgroups.

## Key secondary outcome(s)

1. Difference in forced oscillation technique (FOT) parameters (respiratory resistance [Rrs], Rrs6, dRrs/df, reactance [Xrs]) and Rint parameters and salbutamol rescue medication between treatments in the 3 subgroups
2. Difference in additional rescue treatments between treatments
3. Comparison of the adverse events between treatments
4. Comparison of the number of socio-economic consequences of the pulmonary problems
5. Difference in eosinophil values between treatments

**Completion date**

01/12/2005

## Eligibility

**Key inclusion criteria**

1. Children aged 2 to and including 5 years with asthma or asthma-like symptoms of sufficient severity to justify the use of prophylactic treatment
2. A signed and dated written informed consent is obtained from both parents or the subject's legally acceptable representatives prior to study participation
3. Patients and their parents should be able to perform the study according to the protocol and use the study and rescue medication
4. Parents should agree and be capable to fill out daily record cards and the questionnaires

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

2 years

**Upper age limit**

5 years

**Sex**

All

**Key exclusion criteria**

1. Patients who are currently using systemic or inhaled corticosteroids or leucotriene antagonists
2. Patients who have used in the 2 months prior to visit 1 oral corticosteroids or in the 4 weeks prior to visit 1 inhaled corticosteroids or leucotriene antagonists
3. Patients who have been hospitalized for their asthmatic symptoms in the two weeks prior to visit 1
4. Patients who have known respiratory disorders other than asthma (e.g. broncho-pulmonary dysplasia, cystic fibrosis, tuberculosis etc.)
5. Patients who have known clinical and laboratory evidence of serious uncontrolled systemic

disease

6. Patients with known anatomical abnormalities of the airways
7. Patients who are suspected to be hypersensitive to one of the drugs involved in this study
8. Patients who use systemic medication that interferes with pulmonary control
9. Patients previously randomized in this study
10. Patients who are currently participating in another clinical trial
11. When the physician considers it to be the patient detriment to participate in the study
12. Exacerbation of asthma or asthma-like symptoms that has to be treated with inhaled or systemic corticosteroids during the run-in period

**Date of first enrolment**

01/09/2002

**Date of final enrolment**

01/12/2005

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

**Beatrix Children's Hospital**

Groningen

Netherlands

9700 RB

## Sponsor information

**Organisation**

Merck Sharp and Dohme BV (Netherlands)

**ROR**

<https://ror.org/05y28vr04>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Merck Sharp & Dohme BV (SING-NET-59-01) (Netherlands)

# Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration