ISRCTN38475879 https://doi.org/10.1186/ISRCTN38475879

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

Submission date
08/06/2005

Registration date
20/07/2005

Last Edited
11/09/2009

Recruitment status
No longer recruiting

Overall study status
Completed

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
N/A

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

Secondary study design
Multi-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/09/2002

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

Age group
Child

Lower age limit
2 Years

Upper age limit
5 Years

Sex
Both

Target number of participants
150

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)

Sponsor details
Postbus 581
Haarlem
Netherlands
2003 PC

Sponsor type
Industry

ROR
https://ror.org/05y28vr04

Funder(s)

Funder type
Industry

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

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