The predictive value of the acute effect of montelukast on an exercise challenge test for the outcome of longterm treatment with montelukast

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What is the correlation between change in % fall in FEV1 (*FEV1) after an exercise challenge 20h after a single dose of montelukast and after 4 weeks of treatment with montelukast?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON34924

Source
ToetsingOnline

Brief title
SD-MLK

Condition

- Bronchial disorders (excl neoplasms)

Synonym
exercise induced bronchoconstriction

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: farmaceutische industrie,Merck Sharp &

Dohme (MSD)

Intervention

Keyword: asthma, bronchial hyperresponsiveness, exercise induced bronchoconstriction, leukotriene receptor antagonist

Outcome measures

Primary outcome

Correlation between change in ΔFEV1 after a single dose of montelukast and

after 4 weeks of treatment with montelukast.

Secondary outcome

The predictive value for a response to montelukast after 4 weeks of treatment

(defined as ΔFEV1 < 15%) of:

- baseline FEV1

- symptom score on ACT

- IgE

- positive RAST test

Study description

Background summary

Asthma is a heterogeneous disease and clinical phenotypes are highly variable. This is exemplified in the variability of patients* responses to medications such as montelukast. It is a critical clinical question whether a particular therapy will be effective in an individual child with symptoms of asthma. At the moment, there is a lack of diagnostic tools to assess this individual responsiveness.
Montelukast is a leukotriene receptor antagonist (LTRA) used as prophylaxis for exercise induced bronchoconstriction (EIB). EIB occurs in the majority of asthmatic children and is a reflection of airway hyperresponsiveness (AHR). A single dose of montelukast provides significant protection against EIB as soon as 2 hours after dosing. This rapid response shows variability similar to the

variable responsiveness observed in long term treatment. We hypothesized that the effect of a single dose of montelukast on EIB could predict the effect of long term therapy with montelukast on EIB.

Study objective

What is the correlation between change in % fall in FEV1 (*FEV1) after an exercise challenge 20h after a single dose of montelukast and after 4 weeks of treatment with montelukast?

Study design

study is of a prospective, open-label design without a control group.

Intervention

All children will be treated with montelukast 5 mg (children aged 12-14 years) or 10 mg (children aged >= 15 years) once daily for 4 weeks.

Study burden and risks

EIB is an entity that occurs in most children with asthma and has a great influence on their quality of life. Adults usually perform planned exercise and can take a short acting bronchodilator agent as prophylaxis. Children more often perform exercise that wasn't planned in advance and therefore do not always use prophylactic inhalation therapy. Prophylactic maintenance therapy such as montlukast is therefore more useful in children. We expect treatment with montelukast will improve pulmonary function, decrease symptom scores and diminishes *FEV1 after exercise. Side effects of montelukast are usually mild. Children will perform an Asthma Control Questionnaire and 3 exercise challenges. An exercise challenge can cause serious dyspnoea. However, children with EIB experience this every time they perform exercise and generally consider this as a minimal burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

- Age between 12-18 years
- Clinical history of allergic asthma and exercise induced bronchoconstriction
- Ability to perform reproducible lung function tests, i.e. coefficient of the predicted value variation in 3 of 5 consecutive measurements < 5%
- Ability to run on a treadmill for 8 minutes
- Maximal FEV1 > 70% of predicted value

Exclusion criteria

- Other pulmonary or cardiac illnesses
- Maximal FEV1 < 70% of predicted value
- Use of systemic corticosteroids, antihistamines, cromoglycates, anticholinergics in two weeks prior to or during the study
- Use of long acting bronchodilator agents 24 hours before testing
- Use of short acting bronchodilator agents 8 hours before testing
- Hospitalization due to asthma exacerbation in past month
- Other changes in asthma medication during treatment period
- Upper or lower respiratory tract infections during treatment period
- Deviation of the FEV1 before the subsequent exercise challenges of more than 12 % from baseline FEV1

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2010
Enrollment:	19
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	singulair
Generic name:	montelukast sodium
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-02-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	22-04-2010
Application type:	First submission

Review commission: METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-016904-21-NL
CCMO	NL30374.044.09