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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23949

Source
NTR

Brief title
SD-MLK

Health condition

asthma
exercise induced bronchoconstriction
leukotriene receptor antagonist

Sponsors and support

Primary sponsor: dr. B.J. Thio
Medisch Spectrum Twente
Afdeling kindergeneeskunde
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Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Correlation between change in postexercise fall in FEV1 after a single dose and after 8 weeks of treatment with montelukast.

Secondary outcome

The predictive value for a response to montelukast after 8 weeks of treatment (defined as Î”FEV1 < 15%) of:

1. Baseline FEV1;

2. Symptom score on ACT;

3. IgE;

4. Positive RAST test.

Study description

Background summary

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. We hypothesize that the effect of a single dose on exercise induced bronchoconstriction could predict the effect of longterm treatment on exercise induced bronchoconstriction.

Study objective

We hypoothesize that the effect that a single dose of montelukast has on exercise induced bronchoconstriction correlates with the effect it has after 8 weeks of treatment.

Study design

1. t = 0: Baseline visit;

2. t = 1 wk: Start montelukast;

3. t = 1 wk + 2 hr: Second exercise challenge;

4. t = 9 wk: Third exercise challenge.

Intervention

8 weeks of treatment with montelukast.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 12-18 years;

2. Clinical history of allergic asthma and exercise induced bronchoconstriction;

3. Ability to perform reproducible lung function tests, i.e. coefficient of the predicted value variation in 3 of 5 consecutive measurements < 5%;

4. Ability to run on a treadmill for 8 minutes;

5. Maximal FEV1 > 70% of predicted value.

Exclusion criteria

1. Other pulmonary or cardiac illnesses;

2. Maximal FEV1 < 70% of predicted value;

3. Use of systemic corticosteroids, antihistamines, cromoglycates, anticholinergics in two weeks prior to or during the study;

4. Use of long acting bronchodilator agents 24 hours before testing;

5. Use of short acting bronchodilator agents 8 hours before testing;

6. Hospitalization due to asthma exacerbation in past month;

7. Other medication changes during treatment period;

8. Upper or lower respiratory tract infections during treatment period;

9. Deviation of the FEV1 before the subsequent exercise challenges of more than 12 % from baseline FEV1.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	19
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL1942
NTR-old	NTR2059
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A