

De bescherming van salbutamol tegen inspiratoire luchtwegobstructie ten gevolge van inspanning bij astmatische kinderen

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24513

Source

Nationaal Trial Register

Brief title

N/A

Health condition

Exercise induced asthma/ inspanningsastma.
Inspiratory airflow obstruction/ inspiratoire luchtwegobstructie.

Sponsors and support

Primary sponsor: Medische Spectrum Twenten

Source(s) of monetary or material Support: Stichting Pediatrisch Onderzoek Enschede

Intervention

Outcome measures

Primary outcome

The protective effect of a single regular dose of salbutamol compared with a placebo against inspiratory airflow obstruction in asthmatic children aged 8 till 16 years old.

Secondary outcome

The relation between the protective effect of salbutamol against inspiratory airflow obstruction and EIB.

Study description

Background summary

Exercise induced bronchoconstriction (EIB) is a highly frequent and specific symptom of asthma and also the most bothersome as reported by asthmatic children. Exercise challenge tests (ECT) can identify EIB and are therefore frequently used to diagnose and evaluate asthma. Salbutamol provides excellent protection against EIB, however in daily life prophylactic salbutamol does not always prevent exercise induced symptoms in asthmatic children. A recent study demonstrated that the majority of children with EIB have besides expiratory also inspiratory airflow obstruction. This means that exercise can induce narrowing of the larger airways, possibly as a response to EIB. It is not known to what extent salbutamol can reduce this inspiratory airflow obstruction. Main objective of this study is to investigate if salbutamol protects against inspiratory airflow obstruction.

Study objective

Profylactisch 200ugr salbutamol kan tot 50% beschermen tegen de inspiratoire luchtwegobstructie gemeten in MIF50 die bij de meerderheid van de astmatische kinderen met FEV1 daling tijdens/na inspanning optreedt.

Study design

t= 0: exercise challenge test 1.
t= 1week later: exercise challenge test 2.
Placebo or salbutamol in randomized order.

Intervention

Two exercise challenge test (older children perform this test on a treadmill, younger children on a jumping castle). 15 minutes prior to the test children inhale either 200ugr salbutamol or a placebo.

Contacts

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Eligibility criteria

Inclusion criteria

- Clinical history of EIB.
- Age 8 till 16 years old.
- Ability to jump or run and perform reproducible lung function tests, i.e. coefficient of the predicted value variation in 3 of 5 consecutive measurements < 5%.

Exclusion criteria

- Exacerbation in the last 4 weeks prior to the ECT (hospital admission or use of systemic corticosteroids).
- Use of long acting bronchodilators 24 hours before testing.
- Use of short acting bronchodilators 8 hours before testing.
- Use of leukotriene antagonists 24 hours before testing.

- Other pulmonary or cardiac disorder.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion	
Date:	04-06-2013
Application type:	First submission

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	NL3861
NTR-old	NTR4021
Other	:
ISRCTN	ISRCT wordt niet meer aangevraagd.

Study results

Summary results

N/A