Change of lungfunction after inhaling rescue asthma medication in different amounts in straight up and forward leaning body posture in asthmatic children

No registrations found.

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

Summary

ID

NL-OMON22687

Source
Nationaal Trial Register

Brief title
Body Postures 2

Health condition

asthma
Dutch: astma

Sponsors and support

Primary sponsor: Medisch Spectrum Twente, Enschede
Source(s) of monetary or material Support: Stichting Pediatrisch Onderzoek Enschede

Intervention

Outcome measures

Primary outcome

FEV1, VC, PEF, MEF25 and MEF75 reversibility (%)

Secondary outcome

Possible discomfort body posture measured with VAS scores
Possible side effects of the salbutamol inhalation: number of children complaining about palpitations, tremor, discomfort or rash.

Study description

Background summary

Rationale: The majority of inhaled particles of asthma medication impact in the oropharynx, reducing the dose reaching the lung. This is especially true in children as their airways are smaller. Stretching the airway by a forward leaning posture and head flexed backwards ("sniffing position") may improve pulmonary deposition and clinical effects. In our previous pilot study we observed a greater salbutamol FEV1 reversibility during spirometry in asthmatic children who inhaled in a forward leaning posture compared to the standard body posture.

Objective: Main objective of this study is to investigate if a forward leaning body posture with the head flexed backwards during inhalation increases clinical effects of inhaled medication compared to the standard body posture.

Study design: This will be a randomized single-blind prospective cross-over intervention study.

Study population: Children aged six till sixteen years old, with a clinical history of asthma will be recruited from the outpatient clinic of the paediatric department of Medisch Spectrum Twente, Enschede.

Intervention (if applicable): The intervention is a pulmonary function measurement of spirometry at the pulmonary function lab of Medisch Spectrum Twente, Enschede. Children will perform four times a spirometry reversibility assessment. They will inhale 200µgr or 400µgr salbutamol with an autohaler (AiromirTM) in either the standard body posture or in the leaning forward body posture with their head flexed backwards in a randomized order.

Main study parameters/endpoints: Reversibility of FEV1, VC, PEF, MEF25 and MEF75 in relation to the body posture and head position during inhalation; standard or leaning forward with the head flexed backward.

Study objective

Inhalation of salbutamol in a forward leaning body posture with the head flexed backwards leads to more reversibility of lung function compared to inhalation with the standard body posture during spirometry in asthmatic children.

Study design

01-01-2014 to 01-02-2014: recruiting patients

01-01-2014 to 01-04-2014: spirometry measurements

01-04-2014 to 01-05-2014: analysis data

Intervention

four times spirometry, one time with the inhalation of 200ugr salbutamol in the standard body posture, one time 200ugr salbutamol in the forward leaning body posture with the head flexed backwards and the same two body postures but then with 400ugr salbutamol

Contacts

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Eligibility criteria

Inclusion criteria

- Clinical history of asthma symptoms.

- Age 6 till 16 years old.

- Ability to perform reproducible pulmonary 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 study (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:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	15

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	NL3977
NTR-old	NTR4191
Other	: Body Postures 2
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A