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

Gepubliceerd: 29-09-2013 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22687

Bron
NTR

Verkorte titel
Body Postures 2

Aandoening

asthma
Dutch: astma

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente, Enschede
Overige ondersteuning: Stichting Pediatrisch Onderzoek Enschede

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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%.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2014

Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3977
NTR-old	NTR4191
Ander register	: Body Postures 2
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A