

Small Airway function in obesity and asthma study

Gepubliceerd: 08-10-2015 Laatste bijgewerkt: 15-05-2024

Small airway function differs in obese and non-obese asthmatic patients

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23609

Bron

NTR

Verkorte titel

SANTANA

Aandoening

asthma, obesity

Ondersteuning

Primaire sponsor: Leiden University Medical Center

Overige ondersteuning: third party

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

impulse oscillometry

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: in asthma patients small airway dysfunction is associated with worse symptom control and higher number of exacerbations. Recent studies in obese asthmatic patients show that weight loss improves asthma symptoms and concurrent improvement in small airway function. This could be of clinical importance as extra-fine inhalation medication is available to target this compartment of the lung. However, no gold standard exists to assess small airway function and no study directly compared several tests of small airway function in asthmatic patients with or without obesity.

Objective: to compare small airway function in asthmatic patients with obesity to asthmatic patients without obesity

Study design: single center cross-sectional

Study population: 80 patients with asthma ≥ 6 months, with or without obesity

Main study parameters/endpoints: small airway function as tested by multiple pulmonary function tests.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: This study includes three study visits at the Leiden University Medical Center. During the first visit participants will be subjected to measurement of vital signs, questionnaires will be filled out to obtain information regarding medical history and demography and blood will be drawn. Furthermore pulmonary function tests will be performed, distributed over visit one and two. Finally, sputum collection will take place at visit three.

Doel van het onderzoek

Small airway function differs in obese and non-obese asthmatic patients

Onderzoeksopzet

cross-sectional

Onderzoeksproduct en/of interventie

no intervention

Contactpersonen

Publiek

T.N. Bonten
[default]
The Netherlands

Wetenschappelijk

T.N. Bonten
[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥ 18 who have signed informed consent form prior to the start of the study
- Clinical diagnosis for ≥ 6 months of asthma
- Stable asthma: on a stable dose of asthma inhalation medication for at least 8 weeks prior to baseline visit
- Obese (BMI >30) or non-obese (BMI <30)

Asthma was defined according to the Global Initiative for Asthma 2015 guidelines as:

- presence of symptoms

and

- an increase of $\geq 12\%$ and 200mL in FEV1 after salbutamol
or

- a positive provocation test (methacholine PC20 $<8 - 16\text{mg/ml}$)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Change of asthma inhalation medication in the past 8 weeks before visit 1
- Asthma exacerbation (defined as use of oral or intravenous corticosteroids and/or antibiotics) in the past 8 weeks before visit 1
- Smokers: current ≥ 10 cigarettes per day or ≥ 10 pack years
- Diagnosis of COPD
- Pregnancy, as reported by the participant
- Clinical or functional uncontrolled respiratory- or other disease that might, in the judgement of the investigator, compromise the results or interpretation of the study
- Current- or less than 1 month from baseline participation in interventional clinical trial with inhalation drugs
- Inability to comply with study procedures

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving nog niet gestart
(Verwachte) startdatum: 01-01-2016
Aantal proefpersonen: 80
Type: Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45982

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5256
NTR-old	NTR5546
CCMO	NL54867.058.15
OMON	NL-OMON45982

Resultaten

Samenvatting resultaten

n.a.