Pulmonary rehabilitation and self-management in obese patients with asthma.

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Pulmonary rehabilitation (PRH) and self-management support (SMS) is effective in terms of asthma control compared to standard care in obese patients with suboptimally controlled asthma.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22052

Bron
NTR

Verkorte titel
OBAS 2.1

Aandoening

Asthma
Obesity
Pulmonary rehabilitation
Self-management

Astma
Obesitas
Longrevalidatie
Zelfmanagement

Ondersteuning

Primaire sponsor: Sint Franciscus Gasthuis (SFG)
Overige ondersteuning: Stichting ontwikkeling en wetenschap SFG, Chiesi, Novartis,

GlaxoSmithKline

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Asthma control (asthma control questionnaire)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Asthma is a serious health problem with increasing prevalence in the world. It is a chronic disease which is characterized by episodes of reversible airway obstruction due to underlying chronic airway inflammation and airway hyperresponsiveness to different bronchial stimuli. Evidence indicates that reduced physical activity may be associated with the severity of asthma and the increasing asthma prevalence (Rusmussen F et al. ERJ). Several studies have shown that physical activity improves asthma control and the quality of life of asthma patients. However, physical training does not lead to improved lung function. Obesity, is another important factor that increases the risk of asthma and is related to the severity of asthma. Compared to normal, lean asthma patients, obese asthma patients have more missed school days per year, a lower peak flow, a higher need of inhalation medication and less often acceptable asthma control. The relationship with atopy, allergic rhinitis and bronchial hyper reactivity, however, is less clear. Weight-reducing measures show a beneficial effect on lung function, asthma symptoms, medication use and exacerbation rate. Since, obesity and decreased physical activity level both contribute to the asthma disease burden, a life-style intervention program with multifactorial approach is necessary in the treatment of obese asthmatics.
Pulmonary rehabilitation is a broad therapeutic concept, and can be seen as a life-style and a self-management support intervention. It is an ideal setting to address the needs of people with obesity-related respiratory disorders and individuals with lung disease in whom obesity is also contributing to functional limitation. Data on the effect of pulmonary rehabilitation and self-management support in obese patients with respiratory disorders are limited. In this study we want to investigate the impact of pulmonary rehabilitation with and without self-management support on asthma control and physical condition in obese patients with suboptimally controlled asthma.

Objective:

To determine whether pulmonary rehabilitation (PRH) and self-management support (SMS) is effective in terms of asthma control compared to standard care in obese patients with suboptimally controlled asthma.

Secondary aims of the study are:

- To assess whether pulmonary rehabilitation and self-management support is feasible in obese asthma patients.

- To determine whether pulmonary rehabilitation and self-management support in obese asthma patients has a beneficial effect on their quality of life, lung function, level of airway inflammation and physical condition.

- To determine whether pulmonary rehabilitation and self-management support results in improved level of physical activity.

- To assess the usability and acceptance of life style and self-management intervention modules of the web-based PatientCoach platform.

Study design: pilot study, a 3-armed randomised controlled trial. 36 (3x12) obese asthma patients (BMI 30-< 45) with suboptimally controlled asthma (ACQ > 0.75) from our outpatient clinic will be included in the study. Eligible patients will be randomly assigned 1:1:1 to one of the three groups. 1) pulmonary rehabilitation (PRH), 2) pulmonary rehabilitation with self-management support (PRH+SMS) or 3) standard care. Before and after pulmonary rehabilitation (at 3, 6 and 12 months) symptom scores, spirometry and physical effort strain will be measured. Blood will be sampled and sputuminduction will be performed. Patients will be followed until 12 months after pulmonary rehabilitation.

Study population: Obese patients with proven asthma (n= 36). All patients are between 18 and 50 years old and have an asthma control questionnaire (ACQ) score of > 0.75 after optimal inhalation therapy and smoking cessation. The asthma diagnosis is based on the presence of symptoms and bronchial hyperresponsiveness (PD20 metacholine < 1.76 mg).

Intervention (if applicable):

- Pulmonary rehabilitation (PRH): during 12 weeks three times a week a training of 60 minutes under supervision of a physiotherapist, and with counselling of a psychologist and a dietician.

- Internet based self-management program (SMS), PatientCoach, with education, goal-setting, monitoring and action plan during PRH and during 12 months follow-up.

Main study parameters/endpoints:

Asthma symptom score (asthma control questionnaire (ACQ) score) after pulmonary rehabilitation.

Secondary endpoints will be BMI, asthma quality of life (AQLQ), activity level (move-monitor), exercise capacity (6MWD), lung function (FEV1) and airway inflammation (eosinophils and neutrophils in blood and sputum).

Tertiary endpoints will be symptom scores, self-management characteristics (HeiQ) and exacerbation frequency.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Patients are expected to have individual treatment benefit from the study. The study comprises 8 extra visits (see study design paragraph). Most procedures are non-invasive (e.g. spirometry, FeNO measurement, symptom score and quality of life assessment). During the visits blood will be sampled. This procedure is invasive and may be potential harmful as it may lead to bruises, which will resolve spontaneously. Sputum induction is a minimal invasive technique, which is proven safe when performed to guidelines. Nevertheless, saline inhalation may cause bronchosconstriction. To prevent this, a short-acting â2-agonist is given before the procedure, and pulmonary function is monitored during sputum induction for safety reasons, in order to assess excessive bronchoconstriction.

Doel van het onderzoek

Pulmonary rehabilitation (PRH) and self-management support (SMS) is effective in terms of asthma control compared to standard care in obese patients with suboptimally controlled asthma.

Onderzoeksopzet

3,6 and 12 months after pulmonary rehabilitation.

Onderzoeksproduct en/of interventie

Pulmonary rehabilitation (PRH): during 12 weeks three times a week a training of 60 minutes under supervision of a physiotherapist, and with counseling of a psychologist and a dietician

Internet based self-management program (SMS), PatientCoach, with education, goal-setting, monitoring and action plan during PRH and during 12 months follow-up.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age > 18 and < 50 years

BMI > 30 and =< 45

Proven asthma with increased bronchial hyperreactivity

ACQ > 0.75 despite optimized medication use (LABA and ICS)

Ability to perform a lung function test

Ability to use the internet based self-management tool

Ability to parcipate in pulmonary rehabilitation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Significant orthopedic or neurologic problems that reduce mobility

COPD or other pulmonary pathology apart from asthma

Pregnancy

Asthma exacerbation 6 weeks prior to screening requiring a course of oral steroids or antibiotics.

Maintenance therapy with oral corticosteroids
inability to understand dutch instructions.

Smoking or > 10PY in history

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

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

Aantal proefpersonen:	36
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-12-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40249
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4163
NTR-old	NTR4322
CCMO	NL46602.101.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40249

Resultaten

Samenvatting resultaten
N/A