The impact of pulmonary rehabilitation and self-management support on asthma control in obese patients with asthma

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40249

Source
ToetsingOnline

Brief title
Pulmonary rehabilitation and self-management in obese patients with asthma

Condition

- Other condition
- Bronchial disorders (excl neoplasms)

Synonym
Asthmatic bronchitis, overweight

Health condition

Obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Stichting wetenschappelijk Onderzoek Sint Franciscus Gasthuis

Intervention

Keyword: Asthma, Obesity, Pulmonary rehabilitation, Self-management

Outcome measures

Primary outcome

Asthma symptom score (asthma control questionnaire (ACQ) score) 3 months after pulmonary rehabilitation.

Secondary outcome

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, patient utilities (EQ5D5L), self-management characteristics(HeiQ) and exacerbation frequency.

Study description

Background summary

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 and self-management support on asthma control and physical condition in obese patients with not optimally controlled asthma.

Study 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.
- To assess the incremental cost-effectiveness of pulmonary rehabilitation + self-management support as compared to standard care.

Study design

A 3-armed randomised controlled trial. 36 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 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.

Intervention

- 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.

Study burden and risks

The hypothesis of the study is that patient will benefit from the pulmonary rehabilitation and self-management support. 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 β2-agonist is given before the procedure, and pulmonary function is monitored during sputum induction for safety reasons, in order to assess excessive bronchoconstriction.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Age > 18 and <55 years
-BMI >30 ,and =< 45
-Proven asthma (increased bronchial hyperreactivity (PD20 < 1,76 mg))
-ACQ > 0.75 despite optimized medication use (LABA and ICS)
-Ability to perform a reproducible lung function test
-Ability to use the internet-based self management tool
-Ability to participate in pulmonary rehabilitation
-Consent to 3, 6 and 12 months follow-up visits.
-Patient motivation to achieve the fullest benefit from pulmonary rehabilitation.
-Informed consent

Exclusion criteria

-Significant orthopaedic or neurologic problems that reduce mobility or cooperation with physical training
-COPD or other pulmonary pathology apart from asthma, except for adequate treated OSAS with a AHI < 5.0.
-Inability to understand written and oral Dutch instructions.
-Pregnancy
-Asthma exacerbation in 6 weeks prior to screening requiring a course of oral steroids or antibiotics
-Maintenance therapy with oral steroids
-Current smoking (during pulmonary rehabilitation) or > 10 PY in history
-Participation in Pulmonary rehabilitation program in last 2 year before the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-02-2014
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	27-11-2013
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

Approved WMO

Date:	01-08-2014
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22052
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL46602.101.13
OMON	NL-OMON22052

Study results

Date completed: 15-12-2017

Actual enrolment: 35