Obesity and asthma: effect of training on top of surgery

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21509

Source
NTR

Health condition

Asthma
Obesity
Pulmonary rehabilitation
bariatric surgery
Life style

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
LUMC
Source(s) of monetary or material Support: Chiesi Pharmaceuticals, novartis, GlaxoSmithKline, Stichting Ontwikkeling en Wetenschap interne specialismen Sint Franciscus Gasthuis

Intervention

Outcome measures

Primary outcome

Symptom scores (asthma control questionnaire (ACQ)), 3 months after bariatric surgery.

Secondary outcome

BMI, Asthma-related quality of life (AQLQ), activity level (move-monitor), lung function (FEV1), exercise capacity (6MWD), postoperative complications, cancelled surgeries, inflammation (blood). Tertiary endpoint are symptoms scores, patient utilities (EQ5D5L), postoperative complications, cancelled surgeries and the incremental cost-effectiveness of pulmonary rehabilitation + laparoscopic bariatric surgery as compared to laparoscopic bariatric surgery alone.

Study description

Background summary

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.

Study objective

Pulmonary rehabilitation prior to bariatric surgery is effective by means of outcome (asthma control, complications, recovery, physical condition, quality of life) after the bariatric surgery.

Study design

After PRH
3 months after surgery
6 months after surgery
12 months after surgery

Intervention

Pulmonary rehabilitation: 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. Laparoscopic bariatric surgery: either a gastric sleeve gastrectomy or a Roux-and-Y gastric bypass surgery. During the surgery, subcutaneous and visceral fat tissue biopsy will be performed for analysis.

Contacts

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Eligibility criteria

Inclusion criteria

-Age > 18 and <50 years
-Acceptable operative risk
-ACQ > 0.75 despite optimized medication use (LABA and ICS)
-BMI > 35 kg/m2 with a maximum weight of 150 kg
-Ability to perform a reproducible lung function test
-Ability to participate in pulmonary rehabilitation
-Approval for 3 , 6 and 12 months follow-up visits, and patient motivation to achieve the fullest benefit from pulmonary rehabilitation.
-Informed consent

Exclusion criteria

-Significant orthopedic 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
-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 Rehabilition 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)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	35
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-01-2014
Application type:	First submission

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	NL4262
NTR-old	NTR4398
Other	: OBAS 2.0

Study results