Effect of pre-surgical pulmonary rehabilitation on outcomes of bariatric surgery in morbidly obese patients with asthma

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To determine whether pulmonary rehabilitation prior to bariatric surgery leads to improved and sustained asthma control (ACQ) as compared to bariatric surgery alone in patients with morbid obesity and not optimally controlled asthma.Secondary aims...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON40508

Source
ToetsingOnline

Brief title
Obesity and asthma: effect of training on top of surgery

Condition

- Appetite and general nutritional disorders
- Bronchial disorders (excl neoplasms)

Synonym
Bronchial asthma, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Chiesi Farmaceutici,GlaxoSmithKline,Novartis,Sint Franciscus Gasthuis;stichting wetenshappelijk onderzoek. Subsidieaanvragen Fonds NutsOhra en stichting Janivo zijn ingediend.

Intervention

Keyword: Asthma, Bariatric surgery, Morbid obesity, Pulmonary rehabilitation

Outcome measures

Primary outcome

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

Secondary outcome

Secondary endpoints are 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

The prevalence of obesity has dramatically increased in the Netherlands over the last years. On average, the percentage of subjects with overweight (BMI> 25 kg/m2) has increased more than 50% during the last 30 years. In 2010, 10% of

the Dutch men and 13% of the Dutch women had obesity (BMI>30 kg/m2) (Centraal Bureau voor Statistiek, Permanent Onderzoek LeefSituatie (CBS-POLS)). Epidemiological studies have shown that obesity increases the risk of asthma and is related to the severity of asthma. In a previous study we have demonstrated that bariatric surgery has a proven beneficial effect on symptoms and lung function in obese patients with asthma. However, bariatric surgery is an expensive therapy and has potential unwanted side-effects and complications. Besides, bariatric surgery does solve the problem of overeating, but it does not address other problems such as behaviour or lifestyle. Therefore, a debate has emerged whether lifestyle adjustment by means of intensive physical training before bariatric surgery can improve the outcomes of bariatric surgery and can decrease the complication rate in these asthmatic patients. Pulmonary rehabilitation is a broad therapeutic concept, and can be seen as a life-style 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 in obese patients with respiratory disorders are limited.
In this study we want to investigate the effect of pre-surgical pulmonary rehabilitation on outcomes of bariatric surgery in severe obese patients with not optimally controlled asthma. The hypotheses is that 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 objective

To determine whether pulmonary rehabilitation prior to bariatric surgery leads to improved and sustained asthma control (ACQ) as compared to bariatric surgery alone in patients with morbid obesity and not optimally controlled asthma.

Secondary aims of the study are:

- To determine whether pre-surgical pulmonary rehabilitation in severe obese asthma patients has a beneficial effect on their quality of life, lung function and physical condition.
- To assess whether pulmonary rehabilitation is feasible in morbidly obese asthma patients.
- To determine whether pre-surgical pulmonary rehabilitation results in improved physical activity level.
- To determine whether pulmonary rehabilitation prior to bariatric surgery results in less peri-operative complications.
- To assess the incremental cost-effectiveness of pulmonary rehabilitation + laparoscopic bariatric surgery as compared to laparoscopic bariatric surgery alone.
- To determine whether pulmonary rehabilitation results in a

lower degree of systemic inflammation in obese asthma patients before and after bariatric surgery.
-- To determine the relationship between bronchial inflammation in obese asthmatics and the low-grade systemic inflammation in obesity.

Study design

Randomized controlled trial. Thirty-five morbidly obese asthma patients will be randomized (2:1) to either 12 weeks of pulmonary rehabilitation or 12 weeks no intervention before laparoscopic bariatric surgery. Before and after the bariatric surgery symptom scores, spirometry and physical effort strain will be measured. Blood samples will be taken. The total follow-up of the study will be twelve months after bariatric 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.

Study burden and risks

Patients in the intervention group are expected to have individualised treatment benefit from the study. The study comprises nine visits (see study design paragraph). *Visit 0* and *visit 5* are already standard practice for subjects in the bariatric surgery programme of the Sint Franciscus Gasthuis. Also pulmonary rehabilitation is already often practised for patients with uncontrolled asthma despite adequate medication. Most procedures are non-invasive (e.g. spirometry, FeNO measurement, symptom score and quality of life assessment). Only one procedure is invasive and may be potential harmful. During the visits blood samples will be taken on five occasions (60 ml). This may lead to bruises, which will resolve spontaneously.

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
-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)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-03-2014
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2013
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	12-03-2014
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL44519.101.13

Study results

Date completed:	22-07-2016
Results posted:	19-01-2018
Actual enrolment:	4

First publication
19-01-2018