Obesity and asthma: effect of bariatric surgery on lung function, inflammation and quality of life.

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

Summary

ID

NL-OMON33646

Source
ToetsingOnline

Brief title
Interaction mechanisms in obesity and asthma

Condition

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

Synonym
adiposity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Astra Zeneca,GlaxoSmithKline,Merck Sharp & Dohme (MSD),Novartis,subsidie van ziekenhuis;maatschap;bedrijfsleven;onderzoeksfonds

SFG

Intervention

Keyword: Asthma, Inflammation, Lung function, Obesity

Outcome measures

Primary outcome

The group size is powered on the expected change in FEV1/FVC ratio before and after bariatric surgery. Based on our pilot study and the results in the literature we assume that in obese patients with asthma the FEV1/FVC ratio increases from 72% to 75% (SD ± 6).

Secondary outcome

Secondary endpoints are symptom score, FeNO levels and inflammatory parameters (see study design).

Study description

Background summary

The prevalence of obesity has dramatically increased in the Netherlands over the last years. In 7 years, 10% of the population will be obese (BMI > 30). Epidemiological studies have shown that obesity increases the risk of asthma and is related to the severity of asthma. Several mechanisms have been mentioned. In obesity, a reduction in lung volume takes place which also has consequences for airway resistance. In obesity, systemic inflammation is present with a possible effect on the airways. Also gastro-oesophageal reflux symptoms are often prevalent in obesity and could be a possible cause of airway pathology. Finally, links between obesity and asthma could partly be explained by a common genetic background. Bariatric surgery has a beneficial effect on symptoms and lung function in obese patients with asthma. The problem with previous intervention studies is the relative small size and the lack of control groups. In addition, it is unclear whether the observed effect of weight reduction on asthma symptoms is the result of improvement of pathophysiological parameters or a reduction of systemic inflammation, or both.

Study objective

The aim of the study is first to develop knowledge concerning underlying mechanisms that can explain the relationship between obesity and asthma.

Study design

Eighty morbid obese patients (40 with asthma and 40 without asthma) will prior to and half-yearly after bariatric surgery visit the pulmonary department and undergo spirometry, symptom scores, nitric oxide measurement (FeNO) and blood sampling. During surgery, bronchial and visceral biopsies will be taken from the subjects. Bronchoscopy will be repeated 1 year after operation. Expression of inflammatory mediators, such as tumor necrosis factor alpha (TNF-α), IL-6, leptin en adiponectin will be assessed in biopsy material and blood. A non-intervention group of 20 obese asthmatics will serve as controls. They will folow the same procedures as the intervention group except for bronchoscopy. The total follow-up of the study will be one year after surgery.

Study burden and risks

Patients will have no personal benefit from the study. The study comprises six visits (see study design paragraph). The first visit is already standard practice. Most procedures are non-invasive (e.g. spirometry, FeNO measurement, symptom score and quality of life assessment). Two procedures are invasive and may be potential harmful. First, during the visits blood samples will be taken on three occasions (60 ml). This may lead to bruises, which will resolve spontaneously. Second, on visit 3 and 7, bronchoscopies will be performed. The first bronchoscopy will be performed after intubation of the patients. This is regarded as a safe procedure. Since the patients are deeply sedated, they will not be aware of the procedure. The second bronchoscopy will take place 1 year after bariatric surgery. By that time, the expected weight reduction will be 30%, resulting in a substantially lower chance of complications. Several bronchial biopsies (max. 6) will be taken from the central bronchial mucosa. This may cause some minor bleeding, which will often stop spontaneously or may need intervention by cold water installation or xylomethazoline. The risk of major bleeding or pneumothorax after taking central bronchial biopsies is extremely low. Visceral fat biopsies will be collected during laparoscopy and are not considered to add additional risk to the operation.

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 < 50 year.
For the asthma patients: physician diagnosed, persistent asthma
Able to perform a technical correct and reproducable lung function
Acceptable operative risk
BMI > 35 kg/m2.
Approval for 1 year follow-up visits

Exclusion criteria

Smoking > 10 sig/d or > 10 pack years (PY)
COPD or other pulmonary pathology apart from asthma.
Pregnancy
Exacerbation in 4 weeks prior to screening
Use of oral steroids
Psychological instability

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	30-06-2009
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	26-07-2010
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	03-08-2011
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: 24901
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL25637.101.08
OMON	NL-OMON24901