Effect of weight reduction on gastroesophageal reflux in obese subjects

Published: 29-07-2008
Last updated: 06-05-2024

The primary aim of this study is to assess the effect of weight loss in obese subjects, brought about by non-surgical methods, on all types of gastroesophageal reflux (gaseous, liquid and mixed, acid and nonacid), as measured by ambulatory pH/...

Ethical review	Not approved
Status	Will not start
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON32499

Source
ToetsingOnline

Brief title
Reflux and Obesity

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
GERD, reflux

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: GERD, impedance, manometry, obesity

Outcome measures

Primary outcome

The change in reflux symptoms and objective measurements of gastroesophageal reflux (time pH < 4, number of reflux episodes) before and after 10% weight loss.

Secondary outcome

- Basal LES pressure
- Incidence of TLESR's
- Number of acid and non-acid ('weakly acidic') reflux episodes
- Symptom Association Probability
- Diary Report

Study description

Background summary

A high body mass index (BMI) has been shown to be associated with an elevated risk of gastroesophageal reflux disease (GERD). A specific dose-relationship between increasing BMI and the prevalence of GERD has been demonstrated. Weight loss, along with other life style advice, is often recommended as part of the first-line management of gastroesophageal reflux. However, the beneficial effect of weight reduction has not been demonstrated unequivocally.

Study objective

The primary aim of this study is to assess the effect of weight loss in obese subjects, brought about by non-surgical methods, on all types of gastroesophageal reflux (gaseous, liquid and mixed, acid and nonacid), as measured by ambulatory pH/impedance monitoring.
The secondary aim of the study is to investigate the effect of weight reduction

on reflux symptoms and on the mechanisms underlying reflux.

Study design

In a prospective study the subjects will undergo two assessments to investigate the severity of their gastroesophageal reflux, reflux symptoms and the mechanisms underlying reflux, once before the start of a weight reduction program and once after a weight loss of at least 10% of their initial weight.

Study burden and risks

Participation in the study implies that the patient has to travel to the UMC Utrecht. At the start of the study and after a weight loss of 10% their gastroesophageal reflux will be assessed with 3-hour stationary esophageal manometry 24 hour pH-metry. The risk associated with these procedures is nil. Careful assessment of reflux might lead to more appropriate therapy than otherwise offered.

Contacts

Public
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Men and women > 18 years of age
- BMI > 30 kg/m2

Exclusion criteria

- Medication that affects the motility of the upper gastrointestinal tract (anti-cholinergic drugs, theophylline, calcium blocking agents, opioids)
- Severe concomitant disease
- Extended abdominal surgery in the past
- Present motility disorders

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	manometer

Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	29-07-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL24064.041.08