Risk acceptation of morbidly obese patients seeking weight loss surgery

Published: 19-11-2015
Last updated: 19-04-2024

Primary objective is to gain insight into risk acceptation of serious adverse events (

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON47496

Source
ToetsingOnline

Brief title
Preference study

Condition

- Other condition
- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

Synonym
Morbid obesitas

Health condition

Morbide Obesitas en bariatrische chirurgie

Research involving
Human

Sponsors and support

Primary sponsor: MC Slotervaart
Source(s) of monetary or material Support: MC Slotervaart

Intervention

Keyword: acceptation, risk, surgery, weight-loss

Outcome measures

Primary outcome

Main study parameter is the maximum accepted risk on serious adverse events

(<30 days).

Secondary outcome

Secondary study parameters are expected weight loss and maximum accepted risk

on mortality, long-term complications and side effects and associations with

specific patient characteristics.

Study description

Background summary

Bariatric surgery and its golden standard, the laparoscopic Roux-en-Y gastric bypass (LRYGB) is currently the only sustainable way to reduce mortality in morbidly obese patients. Like with any other surgical procedure, its risk is predominantly expressed in percentage chance of peri-surgical mortality. Over the course of years, mortality in LRYGB surgery has decreased to less than 1%, which is very low for abdominal surgery of this extent. Therefore, surgical outcome is better expressed in *adverse outcomes*, which has a higher prevalence up to about 4%. Patients seldom have knowledge about long-term complications. Long-term complications and complaints such as abdominal pain, nausea and vomiting lead to emergency department visits in >30% of all patients within 3 years after surgery. Side effects are even more common: 42% of all LRYGB will experience at least one episode of *dumping syndrome* within their first postsurgical year. Ninety-one percent of all female and 67% of all male patients report feeling unattractive due to their surgery. Moreover, more than 60% of the female and 40% of the male patients experience skin problems

(rashes, fungal) due to their excess skin. One-third of the female and one-quarter of the male patients experience pain due to their excess skin. One third of all patients have psychological problems due to their surplus skin.
There is some evidence that patients are well aware of the low mortality risk, there are no studies reporting on willingness to accept serious adverse events, long-term complications and the side effects of LRYGB.
We hypothesize that patients accept unrealistic high risks.
Five to 10% total body weight loss (TBWL) has been proven to be enough to have a diminishing effect on comorbidities. Studies reveal that short-term weight loss outcome is generally 31-38% TWBL and long term TWBL is 25-29%. However, patients expect to lose 38% TBWL in the long term and have indicated to be disappointed with a long term TBWL of 26% or less. We hypothesize that patients overestimate the outcomes of bariatric surgery.

Study objective

Primary objective is to gain insight into risk acceptation of serious adverse events (<30 days) in bariatric surgery. Secondary objectives are the expected weight loss, risk acceptation of mortality, risk acceptation of serious adverse events (< 30 days), risk acceptation of long-term complications, risk acceptation of side effects and if high risk acceptation is associated with specific patient characteristics.

Study design

Cross-sectional, non-interventional study using standard gamble and treatment trade off methods.

Study burden and risks

The interview will take one hour and will be scheduled at the day of the patient*s last routine screening visits. The patient will not benefit from participation, except for being very well informed about the outcomes of LRYGB. The interview contains sensitive topics such as mortality and adverse outcomes; the patient might experience discussing these matters as a burden. We emphasize that facts and figures about the results of the operation are a mandatory component of every informed consent. If we gain more knowledge on the willingness to accept a certain risk in patients seeking weight loss surgery and by which factors this accepted risk is influenced, we might be able to inform patients better. This way, we will be able to limit the naïve acceptance of a certain surgical risk for a possibly disappointing outcome.

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 18-65
Seeking weight loss surgery
written informed consent

Exclusion criteria

Incapability to complete Dutch questionnaires or to engage in a Dutch interview due to insufficient ability to understand or speak the Dutch language
No written informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	19-11-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	01-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	23-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL55344.048.15