

Left Ventricular Ejection Fraction before and after bariatric surgery

Published: 21-05-2014

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Primary objective: Increase in left ventricular ejection fraction after bariatric surgery
Secondary objectives: Reduction of paracardial fat after bariatric surgery
Reduction of visceral abdominal fat after bariatric surgery
Reduction of hepatic steosis...

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

Summary

ID

NL-OMON40367

Source

ToetsingOnline

Brief title

LVEF before and after bariatric surgery

Condition

- Other condition
- Heart failures
- Gastrointestinal therapeutic procedures

Synonym

fatness, Obesity

Health condition

(Morbide) Obesitas

Research involving

Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis

Source(s) of monetary or material Support: Maasstad ziekenhuis;afdeling radiologie
Maasstad ziekenhuis;Afdeling interne geneeskunde Maasstad ziekenhuis

Intervention

Keyword: Bariatric surgery, LVEF, MRI

Outcome measures

Primary outcome

Increase in left ventricular function after bariatric surgery.

The most important variables are not clear/uncertain due to a lack of relevant literature regarding the primary objective in combination with a MRI of the heart.

Secondary outcome

Differences in certain levels in blood samples

Reduction of paracardial fat after bariatric surgery

Reduction of visceral abdominal fat after bariatric surgery

Reduction of hepatic steosis after bariatric surgery

Increase in compliance of the thoracic aorta

Anthropometric measurements before and after bariatric surgery

Differences in measurements between the types of bariatric surgery

Study description

Background summary

In the medical world it is known that there are multiple pathophysiological processes within the body of morbid obese patients. Due to these processes

people gain significantly amounts of weight which can cause changes in metabolism. One of the best known change is de progressive resistance to insulin which cause (non) insulin dependent diabetes mellitus type II. It is also proven that obesity causes hypertrophy of the left ventricle of the heart and a diminished left ventricular ejection fraction (LVEF) and more cardiac morbidity and mortality.

To objectivate cardial (dys)function there has to be a validated method to measure one of the most important functional paremeters: LVEF.

There are multiple methods like trans thoracic sonography, transesophageal sonography, nuclair imaging and MRI. The method of choice is proven to be an MRI of the heart, which (sometimes with the help of iv-contrast) can measure functional parameters, dimensions of the left ventricle, left ventricular mass, left ventricular ejection fraction and other (patho)physiological processes.

Bariatric surgery triggers an post operative recovery of the diminished left ventricular function and causes a decrease of mass and diameter of the left ventricle, thus a decrease of left ventricular hypertrofy and a increase of LVEF. In this proces, the decrease in BMI seems to be correlated with the amount of decrease in left ventricular mass. After one year there could be a total recovery of diastolic and systolic dysfunction and aortic compliance. The glucose metabolism can even recover significantly to recover completely after substantial weight loss.

Possible explenations of improvement in LVEF may concern a regression of direct toxic effects in adipose patient upon cardiomyocyts and an improved haemodynamics after weight loss. These improvements can be of such order it may provide a alternative for heart transplant in extreme obese patients.

Annually a total of 400 bariatric surgeries is performed at Maasstad Hospital, Rotterdam, The Netherlands. Mostly it concerns a sleeve gastrectomy or a Roux-en-Y gastric bypass. The most post operative finding is loss of body weight, but also a drop in insulin resitance is seen.

Study objective

Primary objective:

Increase in left ventricular ejection fraction after bariatric surgery

Secondary objectives:

Reduction of paracardial fat after bariatric surgery

Reduction of visceral abdominal fat after bariatric surgery

Reduction of hepatic steosis after bariatric surgery

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Study design

The study will be prospective observational amongst obese patients who are qualified for bariatric surgery. A MRI of the heart will be performed once before surgery and three times after bariatric surgery (3, 6, 12 months). With each MRI, blood samples will be taken to investigate the relation of chemical and endocrinological processes in relation with the left ventricular ejection function.

Study burden and risks

Burden:

1. Four times a MRI of the heart (once before bariatric surgery, three times after bariatric surgery after 3, 6 and 12 months).
2. Four times blood samples (with a maximum of 4 times 10 cc)

Risks:

1. Sensations when stepping into the magnetic field of the MRI (iron taste, vertigo)
2. Small haematoma after a vena puncture.

Contacts

Public

Maasstadziekenhuis

Maasstadweg 32
Rotterdam 3079DZ
NL

Scientific

Maasstadziekenhuis

Maasstadweg 32
Rotterdam 3079DZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Age between 18 and 60 years

BMI > 40 kg/m² or BMI > 35 kg/m² with comorbidity (DM, lung problems, joint complaints)

Several registered efforts of weightloss, guarded by a dietician

Exclusion criteria

Age < 18 and > 60 years

Personality disorders / alcohol or drugs abuse

< 5 years of adiposity

No serious attempts of weightloss

Obesity caused by hormonal or metabolic disorders, no willingness for analysis of such disorders or lifelong check-ups

Change in medication to prevent atherosclerosis (statins)

Diameter > 65 cm (MRI diameter)

Standard contra indications for MRI

Congenital heart disease, known cardiomyopathy, ischaemic heart disease, heart infarction, myocarditis.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	07-05-2015
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO	
Date:	21-05-2014
Application type:	First submission
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	NL46652.101.13