Left Ventricular Ejection Fraction before and after bariatic surgery

Published: 21-05-2014
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Primary objective:Increase in left ventricular ejection fraction after bariatic surgerySecundary objectives:Reduction of paracardial fat after bariatic surgeryReduction of visceral abdominal fat after bariatic surgeryReduction 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 bariatic 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 bariatic surgery

Reduction of visceral abdominal fat after bariatic surgery

Reduction of hepatic steosis after bariatic surgery

Increase in compliance of the thoracic aorta

Anthropometric measurements before and after bariatic surgery

Differences in measurements between the types of bariatic 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 (somestimes 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 bariatic surgery

Secundary objectives:
Reduction of paracardial fat after bariatic surgery
Reduction of visceral abdominal fat after bariatic surgery
Reduction of hepatic steosis after bariatic surgery
Increase in compliance of the thoracic aorta
Anthropometric measurements before and after bariatic surgery
Differences in measurements between the types of bariatic surgery

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 monhs). 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 batiatric surgery after 3, 6 and 12 months).
2. Fout 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 punction.

Contacts

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Maasstadziekenhuis

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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 between 18 and 60 years
BMI > 40 kg/m2 or BMI > 35 kg/m2 with comorbidity (DM, lung problems, joint complaints)
Several registrated 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 attemps of weightloss
Obesity caused by hormonal of 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