CARdiac Disfunction In Obesity * Early Signs Evaluation

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Objective with respect to patient care: Obese patients have an increased risk of developing heart failure. By gaining insight on the role of obesity in cardiac dysfunction it will be possible to provide a better risk stratification for the onset of...

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

Summary

ID

NL-OMON43357

Source
ToetsingOnline

Brief title
CARDIOBESE

Condition

- Heart failures
- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
cardiac dysfunction in obesity; reduced function of the heart in overweight

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: subsidie van de BeterKeten;BOF (Bevordering Onderzoek Franciscus) Franciscus Gasthuis

Intervention

Keyword: Biomarkers, Cardiac dysfunction, Echocardiography, Obesity

Outcome measures

Primary outcome

Primary Objective:

To quantify the proportion of early signs of cardiac dysfunction in obese patients scheduled for bariatric surgery; To determine if obese patients scheduled for bariatric surgery have an elevated risk of (early signs of) cardiac dysfunction.

This objective will be studied by comparing parameters of cardiac dysfunction in obesity patients (before bariatric surgery) with age and gender matched healthy controls.

Secondary outcome

Secondary Objective:

To gain insight in the pathophysiology of obesity causing cardiac dysfunction .

This objective will be studied by:

1. relating signs of cardiac dysfunction to specific features of obesity [inflammation, lipids, diabetes, etc.]

2. relating changes from before to one year after bariatric surgery in cardiac dysfunction and metabolic state to each other), in a longitudinal cohort study, comparing parameters of cardiac dysfunction in obesity patients before vs. 1 year after bariatric surgery, as well as the parameters associated with a

change of cardiac dysfunction parameters.

Study description

Background summary

Obesity is one of the most important public health problems in the Western world. In The Netherlands more than 50% of the people between 30 and 70 years is overweight (a BMI of * 25 kg/m2). In14 percent there is even severe overweight (obesity, or a BMI of * 30 kg/m2). Also, the prevalence of heart failure is increasing. Nowadays, almost 30% of Dutch people will develop heart failure in his/her life.
Obesity increases the risk of developing diabetes mellitus, dyslipidemia and hypertension, all risk factors for the onset of heart failure. Obesity itself is also an independent risk factor for development of heart failure, but this so-called "obesity cardiomyopathy" is still insufficiently recognized.
In view of the increasing prevalence of both obesity and heart failure, an important growing overlap of these two clinical entities in the near future is expected. There is currently not enough knowledge about the role of obesity in causing cardiac dysfunction. This impedes adequate risk stratification and treatment of the obese patient.

Study objective

Objective with respect to patient care:
Obese patients have an increased risk of developing heart failure. By gaining insight on the role of obesity in cardiac dysfunction it will be possible to provide a better risk stratification for the onset of heart failure in obese patients. One of the important goals of the research is to identify parameters that at a very early stage are able to show cardiac dysfunction in patients with obesity. The aim will be to prevent heart failure in such high-risk patients through stricter lifestyle interventions and follow-up, possibly bariatric surgery and eventually a more patient-specific drug treatment.

Objective with respect to health care at the population level:
To diseases due to overweight 1.6 billion Euro in 2012 was issued. The most money was spent on heart disease. By allowing heart failure in obese patients to be better diagnosed and treated, these costs can potentially be brought down significantly.

Objective with respect to the working process of the attending physician:
The value of history and physical examination are limited in excluding or demonstration of heart failure in a patient with obesity. Symptoms (fatigue, dyspnea) and abnormalities on physical examination (edema, increased waist

size) can both be caused by obesity and heart failure. Furthermore, biomarkers for heart failure (for example, the natriuretic peptides) can be falsely reduced. The research aims to identify better parameters for determining cardiac dysfunction in patients with obesity.

Study design

The CARDIOBESE study is a combination of both a cross sectional study of obesity patients and age and gender matched healthy controls (primary objective), and a prospective follow-up study of obesity patients undergoing bariatric surgery (secondary objective).

(Primary objective) During one year, prospective inclusion of 100 consecutive obesity patients that undergo bariatric surgery will take place at the Franciscus Gasthuis and Maasstad Ziekenhuis. By means of conventional and advanced echocardiography, laboratory tests, and heart rhythm registration early signs of cardiac dysfunction will be studied. Baseline data of the obesity patients will be compared with a healthy, age- and gender-matched, control group (50 subjects).

(Secondary objective) Associations of cardiac dysfunction with obesity related characteristics (e.g. markers of inflammation, lipids, presence of diabetes) will be investigated. Also, in the obesity patients, the impact of bariatric surgery, and related metabolic changes, on (changes in) cardiac dysfunction will be studied by repeating the tests one year after bariatric surgery. A longitudinal study design is an optimal design to study the intra-personal impact of obesity and bariatric surgery related changes on changes in cardiac dysfunction.

Study burden and risks

The burden for patients participating in this study is relatively low. Patients do not have to make extra visits to the hospital, do not have to undergo extra invasive tests, and treatment of the patients will not be changed or delayed. Nevertheless, patients do have to undergo some extra tests. However, the echocardiogram and holter monitor are harmless and the blood samples will be taken from a venapunction that will be performed anyway (for clinical reasons). Yet, for the study 5 extra tubes will be collected (total 22 ml) at both visits. Also, the controls do have to come to the hospital specially for the study and for them the venapunction is performed solely for the study.

In general, patients and controls will not be informed about the results of the diagnostic tests performed because of participation in the study. This because the vast majority of the results of these tests does not have any known clinical value. However, when there is an unexpected finding that does have clinical relevance (e.g. significant valvular disease or decreased left

ventricular ejection fraction) the patient will be informed.

Since obesity is one of the most important public health problems in the Western world and the prevalence of heart failure is increasing, the risk to and burden for the subjects will be in proportion to the potential value of the research.

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

Obesity patients undergoing bariatric surgery:
BMI * 35 kg/m2, age 18-65 year and informed consent;Healthy controles:
Age 18-65 years and written informed consent

Exclusion criteria

Obesity patients undergoing bariatric surgery:
Known cardiovascular disease.;Healthy controles:
BMI of * 30 kg/m2, known cardiovascular disease.

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):	19-12-2016
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	26-10-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL57318.101.16