Bariatric surgery Evaluation and Assessment of Treatment efficacy in heart failure and preserved ejection fraction - Intervention Trial

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To evaluate the effects of a bariatric surgery strategy on clinical endpoints, cardiac parameters and functional status in patients with obesity (with BMI 32-40 kg/m2) and symptomatic HF with preserved or mildly reduced LVEF in combination with AF.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52120

Source
ToetsingOnline

Brief title
BEAT-IT

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC
- Gastrointestinal therapeutic procedures

Synonym
atrial fibrillation, Heart failure

Health condition

obesitas, boezemfibrilleren

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Atrial fibrillation, Bariatric surgery, Heart failure with preserved or mildly reduced ejection fraction, Obesity

Outcome measures

Primary outcome

The hierarchical occurrence of: 1) all-cause mortality within 2 year, 2)

emergency room visit or hospitalization for HF within 2 year, 3) recurrent

ECG-documented AF, 4) >=30gr decrease in left ventricular (LV) mass at 2 year,

and 5) improvement of >=5 points on the Kansas City Cardiomyopathy Questionnaire

(KCCQ) at 2 year.

Most endpoints refer to objective endpoints (i.e. mortality, decrease of >=30gr

of LV mass and improvement of >=5 points on the KCCQ). An independent endpoint

committee consisting of a heart failure cardiologist and an electrophysiologist

blinded for baseline characteristics and patient* allocation will assess the

other primary endpoints and will allocate whether the endpoint is adequately

scored as being hospitalization/ER visit for heart failure and recurrent atrial

fibrillation. In case of discrepancy, a third independent cardiologist will be

asked.

Secondary outcome

1. To study the effect of bariatric surgery on all individual items of the

hierarchical endpoint.

2. To study the effect of bariatric surgery on echocardiographic parameters

(eg. LVEF, LV diastolic function, left atrial size, right ventricular function,

amount of epicardial fat) at 2 years.

Study description

Background summary

Obesity is amongst the most prominent and robust risk factors of heart failure (HF) with preserved or mildly reduced left ventricular ejection fraction (LVEF). Obesity is also highly prevalent in patients already diagnosed with HF. Once present, obesity is associated with adverse myocardial remodelling, reduced exercise capacity, progression of atrial fibrillation (AF) and impaired cardiac haemodynamics, compared to non-obese patients with a similar HF type. Obesity is therefore suggested to play a pivotal role in the pathophysiology of HF with preserved or mildly reduced LVEF and durable significant weight loss may reduce the negative impact of adiposity on the heart in these patients. However, the treatment of obesity is notoriously difficult and among all treatment options, bariatric surgery is the most durable option. Bariatric surgery is the recommended choice for patients with class III obesity (body mass index [BMI] >40 kg/m2) as it significantly improves long-term obesity-related outcomes, including mortality. Bariatric surgery is also performed in patients with BMI <40 kg/m2 who have additional relevant obesity-related conditions, mainly type 2 diabetes mellitus. Bariatric surgery is primarily performed in the context of reducing the risk for the development of an obesity-related cardiovascular disease, such as HF. Indeed, it was shown that bariatric surgery significantly reduced the risk of both incident HF and incident AF. However, bariatric surgery is also suggested to be a promising therapy for obese patients already diagnosed with HF and/or AF, but no randomized evaluation of the beneficial effects of bariatric surgery in obese patients with HF and/or AF has been performed so far. Hence, bariatric surgery as a treatment for obese patients with HF and/or AF currently has no specific recommendation in the guidelines. We hypothesize that obese patients with HF with preserved or mildly reduced LVEF in combination with AF may also benefit from significant and durable weight loss following bariatric surgery.

Study objective

To evaluate the effects of a bariatric surgery strategy on clinical endpoints, cardiac parameters and functional status in patients with obesity (with BMI 32-40 kg/m2) and symptomatic HF with preserved or mildly reduced LVEF in combination with AF.

Study design

Multicentre, prospective, randomized controlled, open-label clinical trial

Intervention

An Intervention group receiving bariatric surgery will be compared to a Control group receiving standard of care. Both groups will be randomized in a 1:1 fashion.

Study burden and risks

Patients in the Intervention group will be exposed to increased risk on peri-procedural complications (e.g. bleeding and wound infection) and major complications following bariatric surgery (e.g. including anastomotic leakage, thrombosis and pulmonary embolism). The total incidence of minor complications (i.e. Clavien Dindo class I-II) in 2019 in The Netherlands was 2.3%. For severe complications (i.e. Clavien Dindo class III-V), the incidence rate in 2019 in The Netherlands was 1.9%. The incidence of severe complications was 1.6% for age <65 years and 2.7% for age >=65 years. Overall mortality rate following bariatric surgery (i.e. Clavien Dindo class V) in The Netherlands was 0.0% in 2019 (DATO Bariatric Surgery Report 2019 https://dica.nl/jaarrapportage-2019/dato). Of course the patients in the Control group are not exposed to this peri-procedural risk. However, there are currently no therapies available that have been proven beneficial in reducing mortality and morbidity for patients with HF with preserved or mildly reduced LVEF. With this study design, the beneficial effects of bariatric surgery can be evaluated. If bariatric surgery is indeed beneficial in terms of clinical endpoints, cardiac parameters and functional status, bariatric surgery for obese patients with HF with preserved of mildly reduced LVEF may be a valuable treatment option in the future to improve their prognosis and functional status.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Signs and symptoms of HF according to the European Society of Cardiology guidelines.
2. Left ventricular ejection fraction >=40%.
3. HFA-PEFF score >=5 or HFA-PEFF score 2-4 in combination with positive stress test
4. Between 45 and 70 years of age.
5. BMI 32-40 kg/m2.
6. Paroxysmal or persistent AF with a rhythm control strategy.
7. Willing to undergo both treatment strategies.
8. Written informed consent

Exclusion criteria

1. BMI >=40 kg/m2.
2. BMI <32 kg/m2.
3. Patients unwilling or unable to sign informed consent.
4. More than moderate mitral valve regurgitation/aortic valve regurgitation.
5. More than mild mitral valve stenosis/aortic valve stenosis.

6. Inadequate echocardiographic window for the assessment of LV mass index and/or the echocardiographic criteria needed for the HFA-PEFF score
7. History of myocardial infarction, myocarditis, any invasive cardiac intervention (e.g. surgery, percutaneous coronary intervention, ablation) or stroke, <3 months before inclusion.
8. Scheduled for AF ablation.
9. Complex congenital heart disease.
10. Negative treatment advise from a specialized psychiatrist due to non-stabilized psychotic disorders, severe depression and/or personality disorders.
11. Patients unable to care for themselves or who are unable adapt to inherent life-style changes following bariatric surgery.
12. Any medical condition that limits life span <2 years.
13. Diseases requiring long term use of anti-inflammatory treatments.
14. The use of medication associated with substantial effects (>5 kg) on body weight.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-07-2024
Enrollment:	108
Type:	Actual

Ethics review

Approved WMO

Date:	03-06-2022

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-04-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL78618.042.21