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Heart Failure and Obesity: Effects of Weight Loss (HOW)

Submission date	Recruitment status
29/09/2006	No longer recruiting
Registration date	**Overall study status**
29/09/2006	Completed
Last Edited	**Condition category**
21/07/2010	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544174250

Study information

Scientific Title

Study objectives
What is the effect of weight loss and weight loss maintenance on heart function (cardiac reserve) in obese heart failure patients? We aim to investigate heart function and cardiac reserve (the ability of the heart to respond to exercise) before and after therapeutic weight loss in obese patients with mild to moderate heart failure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Obesity

Interventions
This is a randomised controlled study of intensive diet with weight loss against non-intervention in obese patients with heart failure. The non-intervention group is included to provide information on the background progression or regression of heart failure without weight loss and in the situation where it is not possible to provide a placebo weight loss diet. Patients will be informed that they may be randomised to this control group and will not be receiving a therapeutic intervention. Since the study is designed to assess the benefit (or harm) of weight loss, it is ethically appropriate for such a non-intervention control group. Since it seems unlikely that there will be significant changes in cardiac function in the non-intervention group over the study period of 16 weeks, randomisation will be 3:1.

The main study has been powered on the basis of published data. The power calculations are estimated on the basis of the difference in peak vO2 measurements. Assuming a peak oxygen

utilisation (VO2) during exercise of 19 (SD 3.9) ml/kg/min 24 subjects will be required to detect a 10% improvement in peak VO2 after weight loss with a p value of <0.05, power 85%). A pilot study in 6 patients (non-randomised, and receiving the intensive diet intervention) will be undertaken before the main study and will be used to provide information to confirm (or alter) the power calculations.

Obese patients with heart failure will be recruited from the cardiology clinic at Addenbrookes hospital. Subjects will be given information leaflets about the study so that they can read and discuss them at home prior to giving consent at a later date (>48 hours). After an initial screening visit, at which patients will give informed consent, measurements will be made of peak VO2, blood parameters, and heart function. Based on these results, patients will be informed whether or not they meet the inclusion/exclusion criteria. If they do, at the subsequent visit (measurement baseline) they will be randomised to the active intervention or control group. They will be randomised to either intensive dietary intervention (intervention group) or observation (control group). Both groups will therefore attend one screening visit, and 3 measurement visits (week 0, 6 and 16). The active intervention group will also attend for weekly and then two-weekly interim visits so that their diet can be monitored and managed. The control group will make only one interim visit at week 10.

Subjects will attend the Clinical Research Facility (CRF) at Addenbrookes Hospital Centre for Clinical Investigation (ACCI) at 9am on the study day. Subjects will stay overnight (i.e. for 36 hours) and all measurements listed will be performed during the stay in the CRF. These are: peak VO2 during supervised exercise on a treadmill, measurements of left ventricular function by either echocardiography or MRI, heart rate variability using standard electronic recording devices, body composition using standard techniques, plasma BNP levels and other blood measures, quality of life measurement by standard questionnaire, and spontaneous physical activity using a commercially available recording device.

A low calorie liquid diet will be provided to the intervention group. This dietary regimen is routinely used to achieve initial weight loss by specialists at weight loss management clinics worldwide and also in the Obesity Clinic at Addenbrookes Hospital. Patients will continue this diet for 6 weeks with regular weekly interim follow up. This will be followed by weight loss maintenance diet, the energy value of which will be calculated from standard equation relating height, weight and age to basal metabolic rate.

This study design will allow us to separate effects from acute weight loss and a stable lowered body weight.

The study has been designed with consultation and involvement of experts in obesity, cardiology, and nutrition. The diet intervention is informed by many years experience, including patient feedback and audit, from the setting of an NHS obesity clinic and other clinical trials. For this reason patient involvement in the design of this study was deemed unnecessary.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Peak oxygen consumption during cardiopulmonary exercise testing (Peak VO2) following acute weight loss (week 6) and weight loss maintenance phase(16 weeks)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2006

Completion date
28/02/2008

Eligibility

Key inclusion criteria
38 patients. Pilot study: 6 patients will be recruited for active dietary intervention. Main study: 24 patients will be recruited for the active dietary intervention and 8 patients for the control.
Inclusion criteria:
1. Obese patients defined at body mass index (BMI) of above 30 and <40 kg/m2 (excessive body weight will preclude exercise and accurate imaging)
2. Stable heart failure patients of NHYA (New York Heart Association) class II or III (patients must be able to undertake exercise testing). Diagnosis of heart failure will be based on standard criteria of symptoms of more than 6 months with confirmed LVEF impairment on echocardiogram
3. Age above 25 and below 70 years (to ensure patients can participate with the exercise etc)

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
38

Key exclusion criteria
1. Unable to give informed consent
2. Subjects with renal impairment defined by creatinine >170 Mmol/l (inappropriate to include patients with more complex
illness in this study).
3. Patients with Diabetes Mellitus on antidiabetic medication (other
than metformin - diet and weight loss would require alteration of insulin or non-metformin diabetes treatment, complicating assessments)
4. Heart failure patients of NHYA (New York Heart Association) class <II or >III (patients must be able to undertake exercise testing)

Date of first enrolment
01/03/2006

Date of final enrolment
28/02/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospitals
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Sponsor type
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Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK) Own Account

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Poster results	abstract: Effects of Rapid Weight Loss and Short-Term Weight Loss Maintenance in Obese Patients with Cardiovascular Risks and/or Heart Failure: a Pilot Study. Myint, KS; Northcott, S; Heck, P; Wright, A;Murgatroyd, P; Dutka, D; Brown, M;Ashby, M; Dhatariya, K; Finer, N. Obesity 16, S155. As part of poster session published	06/09/2012		No	No