PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Effect of an interdisciplinary multimodal long-term weight reduction program on left ventricular diastolic function in morbid obesity

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Left ventricular diastolic heart failure has been repeatedly shown to be associated with obesity and the metabolic syndrome. However, it is not known whether an intensive long-term weight reduction program improves diastolic function. Thus, we investigate whether a long-term weight reduction program is able to improve left ventricular diastolic function in subjects with obesity.

Brief Summary in Scientific Language

Left ventricular diastolic heart failure has been repeatedly shown to be associated with obesity. However, it is not known whether an intensive long-term weight reduction program improves diastolic function. In this prospective longitudinal study, subjects with severe obesity and normal ejection fraction undergo detailed echocardiography, including blood flow and tissue Doppler assessment, as well as NTproBNP and GDF-15 measurements before and after a standardized 52 weeks weight reduction program. We hypothesize that a successfull participation in this weight reduction program improves left ventricular diastolic function. Moreover, we shall to evaluate predictors of diastolic dysfunction in severly obese men and women.

Organizational Data

- DRKS-ID: **DRKS00003087**
- Date of Registration in DRKS: **2011/06/15**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **05/001 , Ethikkommission an der Universität Regensburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **I50.12 - [generalization I50.1: Left ventricular failure]**
- ICD10: **E66.9 - Obesity, unspecified**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>Successful participation in the Optifast-52 weight reduction program (Nestle Healthcare). The Optifast -52 program is a standardized multimodal program, encompassing dietetic treatment, physical activity and behavior therapy. The combination of these elements is leading to an effective weight control. In arm 1 treatment is successful, defined by weight reduction >10% at 3 and 12 months as well as re-gain of weight of <10% related to the minimally achieved body mass achieved by the hypocaloric diet phase.</style>
- Arm 2: <style fontName='DejaVu Sans' isBold='true'>Unsuccessful participation in the weight reduction program, i.e. achieved weight reduction <10% after 3 or 12 months, or weight gain >=10% after hypocaloric diet phase.</style>

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Improvement of diastolic function 1 year after weight reduction

Secondary Outcome

1. predictors of left ventricular diastolic dysfunction in obesity and the metabolic syndrome
2. predictive capability of heart failure biomarkers (NTproBNP, GDF-15) in severe obesity

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/07/20**
- Target Sample Size: **520**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

BMI>30 kg/m2; constant body weight during the last 3 months

Exclusion criteria

pregnancy, consuming illnesses, addiction

Addresses

- **Primary Sponsor**

  Klinik und Poliklinik für Innere Medizin II, Universitätsklinikum Regensburg
  Ms. Priv.-Doz. Dr. med. Andrea Baessler
  Franz-Josef-Strauss Allee 11

Primary Sponsor

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Sources of Monetary or Material Support

■ **Institutional budget , no external funding (budget of sponsor/PI)**

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E-mail: **[---]***
URL: **www.uniklinikum-regensburg.de**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*