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

Trial Description

Title

Evaluation of functional gastrointestinal disorders in a group of bariatric patients

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of this study is to evaluate different gastrointestinal complaints in patients before and after surgery for obesity. For this purpose, a set of standardised questionaries will be analysed. The results will be compared to data from obese patients who do not undergo surgery for obesity.

Due to their growing number and economic importance, obese patients gain increasing scientific attention. Recently, gastrointestinal symptoms like e.g. incontinence have been evaluated in patients undergoing bariatric surgery. However, underlying definitions and results are inconsistent and the available studies give mixed results.

Considering the importance of gastrointestinal symptoms in the general population, those are not adequately investigated in obese patients. However, it must be assumed that gastrointestinal complaints play a major role both in pre- and postoperative bariatric patients.

In this present study, gastrointestinal symptoms and gastrointestinal quality of life of obese patients undergoing bariatric surgery will be analysed by evaluation of standardised, validated questionnaires. Results will be compared to data obtained from obese patients not undergoing bariatric intervention.

Brief Summary in Scientific Language

The aim of this study is to evaluate fuctional gastrointestinal disorders, fecal incontinence and gastrointestinal quality of life in pre- and postinterventional bariatric patients. For this purpose, a set of standardised and validated questionaries will be analysed. The results will be compared to data from obese patients who do not undergo bariatric intervention.

Organizational Data

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DRKS-ID: **DRKS00009268**

- Date of Registration in DRKS: **2015/11/03**
- 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.: **2014-513N-MA , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **E66.12 - [generalization E66.1: Drug-induced obesity]**
- ICD10: **K59 - Other functional intestinal disorders**
- ICD10: **R15 - Faecal incontinence**

Interventions/Observational Groups

- Arm 1: **Obese patients undergoing bariatric intervention. Patients answer questionnaires regarding their gastrointestinal quality of life prior to operation as well as 6, 12 and 24 months after surgery.**
- Arm 2: **Obese patients who do not undergo bariatric intervention. Patients answer questionnaires regarding their gastrointestinal quality of life at the date of enrollement as well as 6, 12 and 24 months after surgery.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Prevention**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

gastrointestinal quality of life (gastrointestinal quality of life index) at the following dates: prior to operation, 6 month, 12 month and 24 months after operation/inclusion.

Secondary Outcome

Frequency of functional gastrointestinal disorders and influence of bariatric intervention measured by Bowel Disease Questionnaire an Cleveland Incontninence Score (prior to operation and 6, 12 and 24 months after inclusion/surgery.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsmedizin Mannheim, Mannheim**
- Medical Center **Alfred-Krupp-Krankenhaus, Essen**
- Medical Center **Städtisches Klinikum Karlsruhe, Karlsruhe**
- Medical Center **St. Franziskus-Hospital Köln, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/05/19**
- Target Sample Size: **270**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

BMI > 35 kg/m2

Exclusion criteria

Capacity for consent lacking in patients, factors opposed to active participation (e.g. ECOG percormance status >=3)

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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

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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.*