

Trial Description

Title

Detection of esophageal mucosal changes after bariatric surgery (Sleeve Gastrectomy and Roux - Y - Gastric Bypass) as part of the aftercare

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

As the numbers of obesity and metabolic surgeries in Germany and worldwide continue to increase, so does the number of publications dealing with long-term patient care or late occurring postoperative complications. One such issue is the development of inflammatory changes in the distal esophageal area to the development of Barrett's mucosa (precancerous lesion) a few years after Sleeve Gastrectomy. Crucial here is that only a part of the patients who have such morphological changes become symptomatic before in the sense of active reflux symptoms. Some of the patients, despite asymptomatic course after surgery, appear to be affected by mucosal changes at the esophagogastric junction. At the present time, only patients who have therapy-resistant reflux symptoms after bariatric surgery are endoscopically screened at our Competence Center for Obesity and Metabolic Surgery (DGAV certified). To cope with the increasing evidence regarding the significant proportion of patients with Barrett's esophagus after Sleeve Gastrectomy, we are currently planning that all patients who were undergoing a Sleeve Gastrectomy at our Center 3 or more years ago to offer an esophagogastroduodenoscopy (EGD) as part of the Aftercare. The examinations do not include any aspects outside of a routine gastroscopy with a procedure according to findings (eg sampling of histology in case of conspicuous mucosa). Patients with obesity after Roux-Y Gastric-Bypass surgery are generally considered as not at risk for the development of GERD, as this surgical reconstruction makes the reflux of stomach acid or bile fluid unlikely. However, publications are already available which also describe morphological mucosal changes after surgery in RYGB patients. An endoscopic follow-up of these patients seems to make sense at least once postoperatively, so that we will also offer control EGD to patients from this treatment group who have undergone surgery in our Center.

Our group would like to document the results of the Aftercare endoscopy, after appropriate additional information of the patients, and to subsequently evaluate it scientifically with regard to prevalence of changes of the esophageal mucosa after bariatric interventions. It is intended to assess the value of a routine endoscopy within the usual care of bariatric patients.



Organizational Data

- DRKS-ID: **DRKS00016569**
- Date of Registration in DRKS: **2019/03/08**
- 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.: **2019-1105N , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **K21 - Gastro-oesophageal reflux disease**
- ICD10: **K22.7 - Barrett oesophagus**
- ICD10: **C15 - Malignant neoplasm of oesophagus**

Interventions/Observational Groups

- Arm 1: **Esophagogastroduodenoscopy after sleeve gastrectomy with possibly sampling in case of macroscopic anomalies - 30 minutes**
- Arm 2: **Esophagogastroduodenoscopy after Roux-en-Y-Gastric-Bypass with possibly sampling in case of macroscopic anomalies - 30 minutes**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Screening**
- Assignment: **Other**
- Phase: **N/A**



Study Type: **Interventional**

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Blinding: [---]*

Who is blinded: [---]*

Control: **Other**

Purpose: **Screening**

Assignment: **Other**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

New mucosal changes after bariatric surgery

The value of a routine endoscopy within the usual care of bariatric patients should be assessed

Secondary Outcome

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Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Universitätsmedizin Mannheim, Mannheim**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/04/01**
- Target Sample Size: **237**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria



■ Gender: **Both, male and female**

■ Minimum Age: **18 Years**

■ Maximum Age: **99 Years**

Additional Inclusion Criteria

Sleeve Gastrectomy at the UMM received in the years 2014 - 2016 or RYGB at the UMM received in the years 2014 - 2016

Exclusion criteria

Study participants unable to give their consent

Addresses

■ 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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Status

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

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Votum Ethikkommission**

* 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.