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

Trial Description

Title

Laparoscopic mesh-augmented hiatoplasty versus fundoplication as a treatment for gastroesophageal reflux disease

Trial Acronym

M*A*S*H - Studie

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of this study ist to compare LMAH (laparoscopic mesh-augmented hiatoplasty) with the standard operation, the LF (laparoscopic fundoplication) concerning controll of reflux, side-effects like gasbloat, dysphagia and qualitiy of life.

Brief Summary in Scientific Language

The aim of this study ist to compare LMAH (laparoscopic mesh-augmented hiatoplasty) with LF (laparoscopic fundoplication) concerning controll of reflux, side-effects like gasbloat, dysphagia and qualitiy of life.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004495**
- Date of Registration in DRKS: **2012/11/09**
- 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**

DRKS-ID: **DRKS00004495**
Date of Registration in DRKS: **2012/11/09**
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.: **211/2006 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1136-0288**

Health condition or Problem studied

- ICD10: **K21.9 - Gastro-oesophageal reflux disease without oesophagitis**

Interventions/Observational Groups

- Arm 1: **LMAH (laparoscopic mesh-augmented hiatoplasty), it is the interventional technique, in which the controll of reflux symptoms only is treated by a lengthening of the esophagus, mesh-augmented rebuilding of the anatomy at the hiatus and an anterior gastropexy in the area of cardia.**
- Arm 2: **LF (laparoscopic fundoplication), it is the standard technique, in this way there is no mesh used to reconstruct the hiatus esophagei. Only a fundoplication is build.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

In first line (main objecitve) we tried to say, if there are less surgical side-effects after laparoscopic mesh-augmented hiatoplasty in comparison with laparoscopic fundoplication. For this wie used 2 questionnaires to find out about disorders and quality of life. We used for disorders the "Gastrointestinal Symptom Rating Scale" (GSRS) and for quality of life the "Gastrointestinal Quality of Life Index" (GIQLI). These two questionnaires were answered before surgery and 3, 12 and 36 month after surgery.

Secondary Outcome

Secondary objective is to say, if the lapaorscopic mesh-augmented hiatoplasty has an equal effect like laparoscopic fundoplication on recurrence rate of reflux: gastroscopy before and 12 month after surgery and 24-hours-acidimetry before and 3month after surgery. PPI (proton-pump-inhibitor)-Need was asked in GSRS-questionnaire before operation, 3, 12 and 36 month after operation.
Process while surgery and after surgery. Re-hospitalisation, pain, pressur of esophagus, complications while surgery, morbidity, Reintervention.
The patients said in the questionnaire how strong they see their pain before operation, 3, 12 and 36 month after operation.
The pressure of esophagus was measured by manometry before and 3 months after surgery.

Countries of recruitment

- DE **Germany**
- CH **Switzerland**

Locations of Recruitment

- University Medical Center **Chirurgische Klinik, Heidelberg**
- Medical Center **Chirurgische Klinik, St. Gallen, Schweiz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2006/10/04**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**

Gender: **Both, male and female**

- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

age over 18 years, endoscopical or acidimetrial proof of gastroesophageal reflux disease, consequent proton-pump-inhibitor therapie for at least 3 months, patient agreement

Exclusion criteria

hiatal hernia type II-IV; surgery in case of recurrence, secundary gastroesophageale reflux disease, achalasia, Zollinger-Ellison-Syndrome, malignant tumour, ASA IV-V(American Society of Anesthesiologists), incompetence linguistical or mental to answer the questionaire

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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E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- 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.*