



Trial Description

Title

Changes of the gastrointestinal microbiome in perioperative patients

Trial Acronym

GIMA-Trial

URL of the trial

[---]*

Brief Summary in Lay Language

The microbiome is the majority of all the microorganisms that colonize humans and in all other lifeforms. Modern techniques for sequencing DNA have enabled researchers to find the majority of these microbes - the majority of them cannot be cultured in a lab using current techniques. The human microbiome may have a role in auto-immune diseases like diabetes, rheumatoid arthritis, muscular dystrophy, multiple sclerosis, fibromyalgia, and perhaps some cancers. The main issue of this study is to figure out how the gastrointestinal microbiome is changing during a perioperative process with antibiotic therapy and if there are any outcome-relevant changes.

Brief Summary in Scientific Language

In this study the influence of an antibiotic therapy (single shot before the operation) on the gastrointestinal microbiome should be observed. Stool samples for a 16S RNA analysis and also all relevant clinical data will be collected in 150 patients undergoing a Whipple operation at the time points preoperative, 1d, 3d, 5d, and 7d. At least we will perform a matched-pair analysis, to compare 20 patients with a non-complicated and 20 patients with a complicated clinical course, to see how the microbiome changes and if there are any outcome-relevant findings.

Organizational Data

- DRKS-ID: **DRKS00008535**
- Date of Registration in DRKS: **2015/10/28**
- 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.: **S-119/2015 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**



Secondary IDs

Health condition or Problem studied

- ICD10: **A41 - Other sepsis**
- ICD10: **C25 - Malignant neoplasm of pancreas**
- ICD10: **Z98 - Other postsurgical states**

Interventions/Observational Groups

- Arm 1: **Stool samples for a 16S RNA analyse and also all relevant clinical data will be collected in 150 patients undergoing a whipple operation at the time points preoperative, 1d, 3d, 5d, and 7d. Additionally an outcome reevaluation will be performed at the days 28 and 90.**

Characteristics

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

Primary Outcome

***Changes in the gastrointestinal microbiome under antibiotic therapy (stool samples: preoperative, 1d, 3d, 5d, 7d)**

***Comparison of the microbiome changes and clinical complications (preoperative, 1d, 3d, 5d, 7d)**

Secondary Outcome

***Comparison of the micobiome changes and outcomerelevance at the timepoints: preoperative, 1d, 3d, 5d, 7d (additionally: reevaluation: 28d, 90d)**



Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Anästhesiologie, Heidelberg**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/11/01**
- Target Sample Size: **150**
- 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

- ***Written consent form of study participant or his appointed representative**
- ***Age > 18 years**
- ***undergoing a whipple-operation**

Exclusion criteria

- ***Non-fulfillment of inclusion criteria**
- ***chronic inflammatory diseases**
- ***antibiotic allergies**
- ***Refusal of participation in the study**

Addresses

- **Primary Sponsor**
Universitätsklinikum Heidelberg

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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URL: [---]*

Status

- Recruitment Status: **Recruiting planned**
- 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.