Trial Description

Title

Influence of the gastrointestinal microbiome on perioperative complications

Trial Acronym

GIMA-2 Trial (gastrointestinal microbiome analytic-2 Trial)

URL of the trial

[---]*

Brief Summary in Lay Language

In the narrower sense, the microbiome refers to the totality of all microorganisms colonizing humans or other living organisms. The composition varies greatly depending on the body region (intestine, oral cavity, mucous membranes, genital organs, etc.). The sequencing of the microbiome by means of next-generation sequencing enables the disclosure of genetic information of a multitude of pathogen species, which would remain completely hidden for over 80% when classical cultures are created.
Based on our own promising preliminary results, the influence of our standard antibiotic therapy, as well as the OP-related changes on the microbiome of the digestive tract will now be investigated with more patients in the follow-up project. It may also be possible to detect changes related to survival, e.g. the correlation with complications during surgery, and to create appropriate therapeutic approaches. In the future, this could mean that these new, more targeted approaches could be used to combat infectious complications in earlier, perhaps even subclinical, stages.
Therefore, stool and plasma samples will be collected at two different times from 500 patients undergoing major visceral surgery (including pancreatic, liver and intestinal surgery). If a complication occurs in the further course of the procedure, an additional stool and plasma sample is collected in addition to the standard clinical procedures (blood cultures, etc.). The stool/plasma samples, as well as the swabs, are then prepared in the laboratory and the pathogen spectrum is identified via a 16S RNA sequencing. The plasma samples are also examined for various biomarkers that detect inflammation in the patient. The basic clinical data is also collected at the respective points in time. After 28, 90 and 180 days, an additional examination will be carried out with regard to survival and health status.

Brief Summary in Scientific Language

In the narrower sense, the microbiome refers to the totality of all microorganisms colonizing humans or other living organisms. The composition varies greatly depending on the body region (gastrointestinal tract, pharynx, mucosa, genital organs, etc.). The sequencing of the microbiome by means of next-generation sequencing enables the disclosure of genetic information of a large number of pathogen species, which would remain completely hidden by more than 80% when classical cultures are created. This opens up completely new diagnostic possibilities for a deeper understanding of pathogen colonization and change in

the context of therapy.
Based on our own promising preliminary results, the influence of our standard antibiotic therapy on the gastrointestinal microbiome as well as the changes caused by surgery will now be investigated in a larger group of patients. Possibly, outcome-relevant changes, such as the correlation with perioperative complications, can be detected and corresponding therapy approaches can be created. In the future, this could mean that infectious complications can be combated in earlier, perhaps even subclinical, stages through these new, more targeted approaches.
Therefore, 500 patients undergoing major visceral surgery (e.g. pancreas, liver, intestinal surgery) will be collected at two different times (preoperatively and on day 5). In addition, two sterile swabs are taken intraoperatively in the surgical area. If a complication occurs in the further course of the procedure, an additional stool and plasma sample (3rd time) is obtained in addition to the standard clinical procedures (blood cultures, etc.). The stool/plasma samples, as well as the swabs, are then prepared in the laboratory and the pathogen spectrum is identified via a 16S RNA sequencing. The plasma samples are also examined for different inflammatory biomarkers. The basic clinical data is also collected at the respective points in time. After 28, 90 and 180 days an outcome evaluation will take place.

Organizational Data

- DRKS-ID: **DRKS00017587**
- Date of Registration in DRKS: **2019/08/13**
- 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-382/2019 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **A41.9 - Sepsis, unspecified**
- ICD10: **T81.4 - Infection following a procedure, not elsewhere classified**

Interventions/Observational Groups

- Arm 1: **Analysis of the microbiome by Next Generation Sequencing of stool/plasma samples (preoperative, 5th day postoperative, if complications additional sample)**

Characteristics

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

Primary Outcome

Perioperative examination of changes in the gastrointestinal microbiome.

Secondary Outcome

Investigation of changes in the microbiome in correlation with clinically relevant complications.

Evaluation of the prognostic significance of microbial analysis.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinikum, Heidelberg**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/09/01**
- Target Sample Size: **500**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

- major visceral surgery operation
- a written declaration of consent by the study participant
- Age >18 years

Exclusion criteria

- Refusal to participate in the study
- Chronic inflammatory bowel disease
- pregnancy

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

** 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.*