

Trial Description

Title

Evaluation of small bowel MRI findings for the prediction of the course of Crohn's disease

Trial Acronym

Prediction of CD course by MRI

URL of the trial

[---]*

Brief Summary in Lay Language

Crohn's disease is a chronic inflammatory disease that can involve the whole gastrointestinal tract. The inflammation can progress to complications like stenoses fistulas that might require surgery. In order to predict the individual course of the disease the knowledge of prognostic parameters is helpful. The involvement of the small bowel seems to be such a predictor.

Magnetic resonance imaging (MRI) is used for the assessment of the small bowel. The planned study evaluates whether small bowel MRI is able to predict the course of Crohn's disease thereafter. To this, the MRI findings are correlated to clinical endpoints.

Brief Summary in Scientific Language

Crohn's disease is a chronic inflammatory bowel disease that runs a disabling course in subset of patients. There is increasing evidence that immunosuppressive therapy can change the course and improve prognosis.

Since particular drugs can induce adverse events and / or produce high costs, only patients at risk should receive those drugs. The inflammatory involvement of the small bowel is discussed as predictor of the course, but diagnostic of the small bowel is difficult and mainly relies on ultrasound and magnetic resonance imaging (MRI).

In a previous study we were able to show that small bowel MRI improves the detection of inflammation and complications.

The planned study is designed to evaluate whether the pattern of small bowel involvement as seen in MRI scan gives a clue for the clinical course thereafter. For this, the MRI scan is correlated with clinical course and endpoints like development of stenoses, fistulas, need for immunosuppressive therapy or surgery.

Organizational Data

- DRKS-ID: **DRKS00011727**
- Date of Registration in DRKS: **2017/03/07**
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Date of Registration in DRKS: **2017/03/07**

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.: **5185-14** , **Ethik-Kommission der Medizinischen Fakultät der Ruhr-Universität Bochum**

Secondary IDs

Health condition or Problem studied

- Free text: **Crohn's disease**
- ICD10: **K50 - Crohn disease [regional enteritis]**

Interventions/Observational Groups

- Arm 1: **Data request (interview) after MRI of the small bowel (e.g. development of stenoses, fistulas, need for immunosuppressive therapy or surgery)**

Characteristics

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

Primary Outcome

Determination of a prognostic relevant pattern of small bowel involvement

Prognostic relevance of small bowel MRI after 2 years

- **Crohn's disease associated surgery**
- **Existence of a stenosis**
- **Existence of a fistula**
- **Existence of immunosuppressive therapy**

Secondary Outcome

Prognostic relevance of small bowel MRI after 5 years

- **Crohn's disease associated surgery**
- **Existence of a stenosis**
- **Existence of a fistula**
- **Existence of immunosuppressive therapy**

Prognostic relevance of small bowel MRI at any time

- **Crohn's disease associated surgery**
- **Existence of a stenosis**
- **Existence of a fistula**
- **Existence of immunosuppressive therapy**

Co-morbidities

Extraintestinal manifestations

Perianal disease

Quality of life

Age

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Berufsgenossenschaftliches Universitätsklinikum Bergmannsheil gGmbH, Bochum**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2017/03/15**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**

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■ Maximum Age: **no maximum age**

Additional Inclusion Criteria

**Diagnosis of Crohn's disease
Small bowel MRI from 01/2003 to 12/2014**

Exclusion criteria

**Contact to patient not possible
Lack of informed consent**

Addresses

■ **Primary Sponsor**

**Berufsgenossenschaftliche Universitätsklinik Bergmannsheil gGmbH Abteilung
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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) **Ethikvotum der RUB**

■ trial protocol (mandatory for transfer to Studybox) **Studienprotokoll**

* 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.