Trial Description

Title

Early MOntoring of REsponse on the therapy of Golimumab (GLM) with fecal calprotectin and trough serum levels in patients with ulcerative colitis. A multicentric, prospective study

Trial Acronym

MORE

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of the study is to expand knowledge of the course of golimumab therapy in patients with moderate to severe ulcerative colitis by means of standard care therapy and assessments. Study participants might contribute to a future early identification of patients which do respond or do not respond to golimumab therapy, respectively.

Brief Summary in Scientific Language

The aim of the study is to expand knowledge of the course of golimumab therapy in patients with moderate to severe ulcerative colitis by means of standard care therapy and assessments. Based on this knowledge an algorithm for the optimized use of golimumab in patients with moderate to severe ulcerative colitis will be generated. The decision tool of the algorithm is based on the data from week 6, calculating the probability for clinical response on week 26.

Organizational Data

- DRKS-ID: DRKS00005940
- Date of Registration in DRKS: 2014/09/23
- 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.: D468/14, Ethikkommission der Christian-Albrechts-Universität zu Kiel

Secondary IDs
Health condition or Problem studied

- ICD10: K51.9 - Ulcerative colitis, unspecified

Interventions/Observational Groups

- Arm 1: In patients with ulcerative colitis fecal calprotectin and serum GLM and anti-GLM level are analyzed. Calprotectin will be monitored in week 0, 2, 6, 14, 22 and 26. GLM level will be monitored in week 2 and 6 and anti-GLM level in week 0, 2 and 6.

Characteristics

- Study Type: Non-interventional
- Study Type Non-Interventional: Other
- 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): No

Primary Outcome

To evaluate a 50% reduction of fecal calprotectin and a positive GLM trough level at week 6 to predict clinical response at week 26.

Secondary Outcome

1. At which point in time is a reduction of 50% of calprotectin a reliable predictor of response?
2. How strong is the correlation between Antibodies-Towards-GLM (ATG) and fecal calprotectin?
3. How strong is the correlation between ATG and Partial Mayo Score?
4. How strong is the correlation between GLM trough level and fecal calprotectin?
5. How strong is the correlation between GLM trough level and Partial Mayo Score?
6. Are serum CRP levels, leucocyte count, hemoglobin levels, thrombocyte count or ferritin levels constraining factors for the clinical response due to GLM treatment?
Countries of recruitment

- DE Germany

Locations of Recruitment

- Doctor's Practice Oldenburg
- Doctor's Practice Münster
- Doctor's Practice Leipzig
- Medical Center Halle Saale
- University Medical Center Lübeck
- Medical Center Lüneburg
- University Medical Center Münster
- Doctor's Practice Kassel

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2014/10/24
- Target Sample Size: 61
- Monocenter/Multicenter trial: Multicenter trial
- National/International: National

Inclusion Criteria

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

Additional Inclusion Criteria

1. Established diagnosis of ulcerative colitis by endoscopical and clinical determination
2. Trial-independent treatment with golimumab according to routine local prescribing practice at the discretion of the investigator
3. Minimum age of 18 years
4. The patient must be capable in communicating sufficiently in German
5. The patient must be able to recognize the nature, significance and scope of the study and must agree in a written informed consent.
6. Increased level of calprotectin (≥100 mg/l or ≥100 mg/kg) within 3 weeks prior to inclusion or existing endoscopic record of a distinct inflammatory response (UCEIS ≥ 3 points).
Exclusion criteria

1. Infectious colitis
2. Treatment with Golimumab outside the label
3. Treatment with Golimumab within the last 3 month

Addresses

- **Primary Sponsor**
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Sources of Monetary or Material Support

- Private sponsorship (foundations, study societies, etc.)
  
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  E-mail: [---]*
  URL: [---]*

Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2018/06/21

Trial Publications, Results and other documents

- Paper Veröffentlichung des Studienprotokolls / Publication of study protocol

* 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.