Trial Description

Title

Exclusive nutritional therapy and intestinal homeostasis in pediatric inflammatory bowel disease

Trial Acronym

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URL of the trial

[---]*

Brief Summary in Lay Language

Exclusive enteral nutrition has a well-estabilshed role for induction of remission in active pediatric inflammatory bowel disease. Nutritional therapy is as efficacious as steroid treatment and achieves mucosal healing for optimal prevention of future relapse. However the exact mechanism of action remains unknown. The aim of this non-interventional study is to elucidate the anti-inflammatory effects of exclusive enteral nutrition on intestinal inflammation, gut microbiota and the immune system. Patients suffering from inflammation will be examined at two timepoints: before and two to six weeks after initiation of therapy. The composition of gut microbial flora will be analysed in stool samples collected during therapy. Peripheral blood and mucosal biopsies are studied for changes in the immune system. The nutritional therapy group is controlled with patients who need to be treated with steroids or biologicals.

Brief Summary in Scientific Language

Inflammatory bowel disease (IBD) is being recognized with increased frequency in children and adolescents. Despite recent advances in the understading of crohn's disease the precise aetiology remains elusive. Several factors contribute to the breakdown of intestinal homeostasis, including genetic factors, the host immune system, and environmental factors such as the gut microbiota.

Optimal therapeutic strategies for the chronic bowel inflammation are aimed to achieve mucosal healing. Exclusive enteral nutrition promotes mucosal healing and is an established therapy for induction of remission in pediatric active crohns disease. However, the mechanism of action of such therapy is still unclear. The aim of the study is to elucidate the regulatory properties of exclusive enteral nutrition on the interactions between the microbiota, the intestinal epithelium and the host immune system.

Organizational Data

- DRKS-ID: **DRKS00003548**
- Date of Registration in DRKS: **2012/02/17**
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Date of Registration in DRKS: **2012/02/17**
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.: **411/11 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **K50.9 - Crohn's disease, unspecified**

Interventions/Observational Groups

- Arm 1: **Non-interventional study with children and adolescents treated for six to eight weeks with exclusive enteral nutrition for induction of remission of active crohn's disease. Before initiation of therapy diagnosis is established. Venipuncture and endoscopy are part of the routine diagnostic workup. Two to six weeks after initiation of therapy the patient will be re-evaluated. Additionally, patients will be asked to provide stool samples.**

- Arm 2: **Treatment of children or adolescents with active crohn's disease with biologicals or steroids. Before initiation of therapy diagnosis is established. Venipuncture and endoscopy are part of the routine diagnostic workup. Two to six weeks after initiation of therapy the patient will be re-evaluated. Additionally, patients will be asked to provide stool samples.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
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Study Type Non-Interventional: **Other**

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Blinding: **[---]***

Who is blinded: **[---]***

Control: **Active control (effective treament of control group)**

- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Parameters will be evaluated before and 2-6 weeks after initiation of therapy:
1. Gut microbiome composition before and during therapy (method: sequencing).
2. Mucosal inflammation on molecular and cellular level (methods: quantitative PCR, immunohistochemistry).
3. Phenotype and Function of peripheral blood mononuclear cells (methods: FACS analysis, ELISA, qPCR).

Secondary Outcome

Clinical and laboratory remission after 2-6 weeks of therapy; methods: history and examination, disease activity score, stool and lab work for inflammatory markers;

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinikum der Universität München, Dr. von Haunersches Kinderklinik, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/02/20**
- Target Sample Size: **20**

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Target Sample Size: **20**

- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **6 Years**
- Maximum Age: **20 Years**

Additional Inclusion Criteria

- Patients suffering from active inflammatory bowel disease and need to be treated with exclusive enteral nutrition therapy, steroids or biologicals;
- Diagnosis confirmed by Porto diagnostic criteria;
- informed consent of patients (> 12 years of age) and parents.

Exclusion criteria

Changes in the immunosuppressive medication during the last three month.

Addresses

- **Primary Sponsor**

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Contact for Scientific Queries

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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URL: **[---]***

Status

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

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- Study Closing (LPLV): **2015/12/15**

Trial Publications, Results and other documents

- Paper **[---]***

** 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.*