Trial Description

Title
Retrospective Observing Refractory Celiac Disease in Germany

Trial Acronym
RCD-study

URL of the trial
http://www.gisg.eu/laufende_register-studien.html

Brief Summary in Lay Language
The proposed study is an retrospective observational study to analyze the prevalent diagnostic and therapeutic pathway for RCD in Germany. At the same time, a register for RCD will be established. Another study goal is to yield an approximation of RCD incidence in Germany.

Brief Summary in Scientific Language
Refractory celiac disease (RCD) is a rare complication of celiac disease, being defined as an enteropathy resembling celiac disease with villous atrophy, crypt hyperplasia, but being refractory to a gluten-free diet (GFD). Refractory states can be either primary (i.e. never having responded to a GFD) or secondary, i.e. the refractory state develops after a significant time of GFD-associated clinical improvement. RCD classification is based on the biology of intraepithelial lymphocytes (IELs) found in the small intestinal lesions and includes RCD type II as an enteropathy with aberrant intraepithelial lymphocytes (IELs) that are clonal in nature and are precursors of T lymphoma cells. Contrary to type II, aberrant (clonal) IELs are not found in RCD type I. Thus, an enteropathy associated T cell lymphoma (EATL) is considered to develop in a high percentage of RCD type II, but not in RCD type I patients. Since treatment of established EATL is mostly unsuccessful and the subsequent disease course is fatal, timely establishment of RCD type II diagnosis is important to impede progression to EATL by medical treatment. However, RCD is very rare (approx. 0.5 cases per 100 celiac patients). Therefore no international diagnostic and therapeutic standard has been established yet. A nation-wide register that can be used for future diagnostic and/or therapeutic studies will allow for establishing prevalent diagnostic and therapeutic approaches for RCD in Germany as a first step towards a better treatment option for this rare condition.

Do you plan to share individual participant data with other researchers?
[---]*
Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: DRKS00006871
- Date of Registration in DRKS: 2014/10/31
- 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.: EA4/047/14, Ethik-Kommission der Charité - Universitätsmedizin Berlin-

Secondary IDs

Health condition or Problem studied

- Free text: Refractory Celiac Disease

Interventions/Observational Groups

- Arm 1: The proposed retrospective study is to analyze the prevalent diagnostic and therapeutic pathway for Refractory Celiac Disease (RCD) in Germany. At the same time, a register for RCD will be established. The data will be collected by applying the paper-bases questionnaire, including the social data of the patient, data of first diagnosis, medication, RCD diagnosis (serology, histology), nutrition therapy, clinical expression (independent on the therapy).

Characteristics

- Study Type: Non-interventional
- Study Type Non-Interventional: Observational study
- Allocation: Single arm study
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Uncontrolled/Single arm
- Purpose: Supportive care
The primary goal is to implement a Germany-wide Registry for Refractory Celiac Disease (RCD) patients.

A questionnaire based observation trial is to be performed associated with the identification of RCD patients. Physicians, treating RCD patients, will fulfill the questionnaire containing data of the chosen diagnostic and therapeutic RCD strategy.

Countries of recruitment

DE Germany

Locations of Recruitment

- University Medical Center Charite, Berlin
- Doctor's Practice Saarbrücken
- University Medical Center Jena
- Medical Center Asklepios Klinik Pasewalk, Pasewalk
- Doctor's Practice Ettlingen
- Medical Center Hufelandklinik, Bed Langensalza

Recruitment
Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 1 Years
- Maximum Age: no maximum age

Additional Inclusion Criteria

Inclusion criteria follow the criteria to diagnose RCD: Enteropathy with villous atrophy and crypt hyperplasia (Marsh IIIa/b/c); Clinically refractory to a gluten-free diet (GFD) for >1 year; If the patient's clinical situation requires medical treatment directed to treatment of malabsorption, definition of RCD can be based on diet-refractory states <1 year:
- enteral / parenteral nutrition
- local or systemic acting steroids
- azathioprin
- other medical therapy directed towards refractory sprue

Exclusion criteria

Exclusion criteria:
- low adherence to a GFD;
- existence of other diseases, that provide an explanation for the clinical symptoms:
  - Small intestinal Crohn´s disease
  - Lamblia
  - Whipple´s disease
  - Common variable immunodefiency (CVID)
  - AIDS-associated enteropathy
  - eosinophilic enteritis
  - Autoimmune enteropathy
  - Radiation-induced enteritis
  - Intestinal tuberculosis

Addresses

- Primary Sponsor
  
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Sources of Monetary or Material Support

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- Private sponsorship (foundations, study societies, etc.)
  
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  URL: http://www.dzg-online.de

Status

- Recruitment Status: Recruiting ongoing
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents
DRKS-ID: DRKS00006871
Date of Registration in DRKS: 2014/10/31
Date of Registration in Partner Registry or other Primary Registry: [---]*

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.