Trial Description

Title
Ibd CAncer and seRious infections in Europe

Trial Acronym
I-CARE

Brief Summary in Lay Language
Inflammatory bowel diseases (IBD) includes Crohn’s Disease and ulcerative Colitis. It is a chronic, disabling, incurable condition that affects 3 million Europeans. Current therapeutic options are limited and comprise 5ASA, immunosuppressive, anti-TNF and Vedolizumab. New treatment strategies, which are specified in European and national guidelines, aimed at an earlier use of TNF antibody in the treatment of IBD. It is planned a multicenter inclusion of 1.000 patients in Germany and a total of 17.600 patients in Europe. Planned observation periode- 3 years.

Brief Summary in Scientific Language
I-CARE is the first observational European prospective study that will provide unique information (safety, efficacy/potential for disease modification, risk-benefit ratio, and healthcare costs) on the long-term use of anti-TNF therapy in IBD, using a predefined standardized follow-up. These real world data will be used to guide clinicians as well as Healthcare authorities to provide the best care for IBD patients by optimizing available therapies. These findings may assist in maximizing benefits and minimizing risks among IBD patients who are candidates for anti-TNF therapy.

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

Description IPD sharing plan
[---]*

Organizational Data
Arm 1: Group 1: IBD-patients with a diagnosis at least 3 months earlier, based on usual radiological, endoscopic or histological criteria, and who have never received biological agents or immunosuppressant before. All 5-ASA and steroids formulations are permitted. During the period of follow-up of 3 years following parameters are evaluated: Demographic, Disease characteristics, family history, personal history, vaccination and infection history, previous & current medication, biological data.

Arm 2: Group 2: IBD-patients with a diagnosis at least 3 months earlier, based on usual radiological, endoscopic or histological criteria, and receiving thiopurines alone. During the period of follow-up of 3 years following parameters are evaluated: Demographic, Disease characteristics, family history, personal history, vaccination and infection history, previous & current medication, biological data.

Arm 3: Group 3: IBD-patients with a diagnosis at least 3 months earlier, based on usual radiological, endoscopic or histological criteria, and treated with anti-TNF therapy alone without any concomitant immunosuppressant. During the period of follow-up of 3 years following parameters are evaluated: Demographic, Disease characteristics, family history, personal history, vaccination and infection history, previous & current medication, biological data.

Arm 4: Group 4: IBD-patients with a diagnosis at least 3 months earlier, based on usual radiological, endoscopic or histological criteria, and treated with anti-TNF therapy in combination with thiopurines or...
methotrexate.

During the period of follow-up of 3 years following parameters are evaluated:
Demographic, Disease characteristics, family history, personal history, vaccination and infection history, previous & current medication, biological data

- **Arm 5:** Group 5: IBD-patients treated with vedolizumab alone and IBD-patients treated with vedolizumab in combination with thiopurines or methotrexate.
  - During the period of follow-up of 3 years following parameters are evaluated:
    - Demographic, Disease characteristics, family history, personal history, vaccination and infection history, previous & current medication, biological data

- **Arm 6:** Group 6 (optional): IBD-patients, treated with Ustekinumab with or without concurrent medication. (Only investigators who treat CD-patients with Ustekinumab). During the period of follow up of 3 years following parameters are evaluated: Demographic, Disease characteristics, family history, personal history, vaccination and infection history, previous & current medication, biological data

### Characteristics

- **Study Type:** Non-interventional
- **Study Type Non-Interventional:** Observational study
- **Allocation:** Non-randomized controlled trial
- **Blinding:** [---]*
- **Who is blinded:** [---]*
- **Control:** Other
- **Purpose:** Health care system
- **Assignment:** Parallel
- **Phase:** N/A
- **Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels):** N/A

### Primary Outcome

The primary objective of I-CARE study is to assess prospectively the presence and the extent of safety concerns (cancers (especially lymphoma) and serious infections risks) for anti-TNF or other biologicals alone or in combination with thiopurines among IBD patients. Safety profile of all steroids formulation will also be analysed. We will stratify the risk of cancers and serious infections according to IBD phenotype and disease activity (clinical, radiologic and endoscopic).
Study duration 4 years: 1 year inclusion period and 3 years follow-up period

### Secondary Outcome

To investigate prospectively the impact of anti-TNF based strategies or other biologicals on the natural history of IBD and their potential for disease modification by collecting validated surrogate markers such as mucosal healing and disease complications such as bowel damage, surgeries and hospitalizations.

To assess the evolution of patient-reported outcomes (PROs) on a yearly basis and
the impact of anti-TNF agents or other biologicals on PROs in IBD. 1 year inclusion period and 3 years follow-up period.

To evaluate the benefit-risk ratio of strategies based on an earlier and wider use of anti-TNF or other biologicals therapy for IBD.

To assess the healthcare costs and cost-efficacy of current therapeutic strategies in IBD.

Study duration 4 years: 1 year inclusion period and 3 years follow-up period

Countries of recruitment

- DE Germany
- BE Belgium
- DK Denmark
- FR France
- UK United Kingdom
- IE Ireland
- IL Israel
- IT Italy
- NL Netherlands
- PL Poland
- RU Russian Federation
- SE Sweden
- CH Switzerland
- HU Hungary

Locations of Recruitment

- University Medical Center Erlangen
- Medical Center Hannover
- University Medical Center Berlin
- other Berlin
- University Medical Center Münster
- Medical Center Friedrichshafen
- Doctor's Practice Minden
- University Medical Center Bochum
- Doctor's Practice **Eschweiler**
- Medical Center **Berlin**
- University Medical Center **Lübeck**
- other **Pinneberg**
- Medical Center **Frankfurt a.M.**
- University Medical Center **Mannheim**
- University Medical Center **Lübeck**
- Doctor's Practice **Berlin**
- University Medical Center **Dresden**
- Doctor's Practice **Andernach**
- Doctor's Practice **Oldenburg**
- Medical Center **Hamburg**
- Medical Center **Landau**
- Doctor's Practice **Herne**
- Doctor's Practice **Altenholz**
- Doctor's Practice **Radebeul**
- Medical Center **Köln**
- Doctor's Practice **Münster**
- Medical Center **Lüneburg**
- Medical Center **Hamburg**
- other **Münster**
- Medical Center **Berlin**
- Doctor's Practice **Potsdam**
- Doctor's Practice **Saarbrücken**
- Doctor's Practice **Kassel**
- Medical Center **Braunschweig**
- University Medical Center **Dresden**
- University Medical Center **Jena**
- Doctor's Practice **Oldenburg**
- Medical Center **Berlin**
- University Medical Center **Jena**
- Medical Center **Berlin**
Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/04/01**
- Target Sample Size: **17600**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

Patient with an established diagnosis of Crohn’s disease, ulcerative colitis or IBD, unclassified made at least 3 months earlier based on usual radiological, endoscopic or histological criteria.

Patient 18 and older accepting to sign the informed participating consent form, stating that he accepts to provide personal details to complete the electronic study documentation as required and to be contacted by a Study Coordinator and his gastroenterologist for the purpose of the study during the entire study period if required.

Exclusion Criteria

Patient unable to sign the informed consent form.
Patient with no regular access to internet.
Patient refusal to sign informed consent form.
Treatment at entry in the study with an immunomodulator different from thiopurines and methotrexate.
Patient previously enrolled in a randomized clinical trial.

Addresses

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Sources of Monetary or Material Support

- Private sponsorship (foundations, study societies, etc.)

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Status

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

Trial Publications, Results and other documents

- Abstract Poster, 12th Congress of ECCO

* 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.