PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

**Understanding the impact of Ulcerative Colitis and its associated disease burden on
patients**

Trial Acronym

ICONIC

URL of the trial

[---]*

Brief Summary in Lay Language

The overall aim of this study is to increase awareness and understanding of the multi-faceted disease burden associated with Ulcerative Colitis (UC), to enable improved UC understanding and Management.

Brief Summary in Scientific Language

**The key objectives are
to describe the multi-faceted burden of disease in recently diagnosed patients with Ulcerative Colitis, to investigate the correlation between patient and physician perception of Ulcerative Colitis disease and to estimate resource utilisation associated with Ulcerative Colitis and investigate the correlation between this and evaluated burden of disease.**

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00009858**
- Date of Registration in DRKS: **2016/01/19**

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Date of Registration in DRKS: **2016/01/19**

- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **41/15 , Ethik-Kommission der Ärztekammer Berlin**

Secondary IDs

Health condition or Problem studied

- ICD10: **K51.9 - Ulcerative colitis, unspecified**

Interventions/Observational Groups

- Arm 1: **This observational study will be performed in a prospective, 24-month follow-up, noninterventional format in UC patients. Patients will be asked to complete five short questionnaires or visual representations to provide an evalution of their perceived illness associated with disease, clinical symptom perception, levels of worry, anxiety and depression and quality of life.**

Characteristics

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

Primary Outcome

• To evaluate Pictorial Representation of Illness and Self Measure (PRISM) as an assessment tool for perceived disease-associated suffering in UC patients, by assessing correlation with Short quality of life in inflammatory Bowel Disease Questionnaire (SIBDQ) and Patient Health Questionnaire (PHQ-9) (quality of life), according to geographical location and disease severity.

Secondary Outcome

• To describe the multi-faceted burden of disease in recently diagnosed Ulcerative Colitis patients.

Countries of recruitment

- DE **Germany**
- AR **Argentina**
- AT **Austria**
- BA **Bosnia and Herzegovina**
- BG **Bulgaria**
- CA **Canada**
- CL **Chile**
- CO **Colombia**
- HR **Croatia**
- CZ **Czech Republic**
- EG **Egypt**
- EE **Estonia**
- FR **France**
- GR **Greece**
- IE **Ireland**
- IL **Israel**
- IT **Italy**
- JP **Japan**
- KW **Kuwait**
- MX **Mexico**
- PT **Portugal**
- RO **Romania**
- RU **Russian Federation**
- SA **Saudi Arabia**
- RS **Serbia**

- SK **Slovakia**
- ZA **South Africa**
- ES **Spain**
- SE **Sweden**
- TR **Turkey**
- UA **Ukraine**
- UK **United Kingdom**
- VE **Venezuela, Bolivarian Republic of**
- SI **Slovenia**

Locations of Recruitment

- other **Multizentrisch in Klinik und Praxis**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/06/19**
- Target Sample Size: **1800**
- 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

• Patients aged ≥ 18 years who have been diagnosed with Ulcerative Colitis ≤ 12 months prior to study inclusion

• Signed a patient authorization form to use and disclose personal health information

Exclusion criteria

[---]*

Addresses

- **Primary Sponsor**

  AbbVie Deutschland GmbH & Co. KG
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  65189 Wiesbaden
  Germany

  Telephone: **0611 1720 3554**
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  E-mail: **stefan.rath at abbvie.com**
  URL: **[---]***

- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/11/09**

Trial Publications, Results and other documents

** 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.*