The efficacy and safety of biosimilar infliximab CT-P13 in IBD: a prospective, nationwide, observational cohort (Biosimilar infliximab in IBD)

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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/9054

EU PAS number
EUPAS9053

Study ID
9054

DARWIN EU® study
No

Study countries
Hungary

Study description
Biosimilars are biologic medicines that enter the market subsequent to an original reference product whose patent has expired. Biosimilar infliximab CT-P13 received EMA approval in 2013 and was granted marketing authorization for all of the indications of the reference product, based on parallel-group clinical trials in rheumatoid arthritis (RA) and ankylosing spondylitis. Therefore, inflammatory bowel diseases (IBD) are considered as extrapolated indications. Concerns have been expressed regarding extrapolated indications. The dosing is different in RA (3 mg/kg b.w.) and in rheumatologic diseases combination therapy is more frequently used, which may influence immunogenicity. As of

May, 2014 the Hungarian National Health Fund only reimburses the biosimilar infliximab for new induction treatment in IBD. New induction is defined as no infliximab treatment in the previous 12 month, switch was not allowed. Data on the safety and efficacy of biosimilar infliximab in clinical practice in IBD is limited so far. Therefore, the aim of the present study was to conduct a prospective, nationwide, multicentre, observational cohort to examine the efficacy and safety of CT-P13 infliximab biosimilar in the induction and maintenance treatment of Crohn's disease and ulcerative colitis. The primary endpoint of the study was early clinical remission at week 14. Secondary endpoints include early clinical response at week 14, steroid-free clinical remission at week 30, sustained clinical remission and response at week 54, early and sustained biochemical response at week 14 and week 54, mucosal healing at week 54 and safety. Consecutive IBD patients starting on infliximab biosimilar were prospectively enrolled and a standardized monitoring strategy was applied. Demographic data, medication history, clinical, laboratory and endoscopic/radiological imaging were collected. Infliximab trough and anti-drug antibodies were measured at regular intervals. Adverse events were registered.

Study status
Ongoing

Research institution and networks

Institutions

Semmelweis University

Hungary
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Institution

Hospital/Clinic/Other health care facility

First Department of Internal Medicine

First Department of Internal Medicine, University of Szeged Szeged, Military Hospital – State Health Centre Budapest, First Department of Medicine, Peterfy Hospital, Budapest, Second Department of Medicine, Zala County

Hospital Zalaegerszeg, Second Department of Medicine, B-A-Z County and University Teaching Hospital Miskolc, Department of Internal Medicine, Csolnoky Ferenc Regional Hospital Veszprem, Second Departement of Internal Medicine, Semmelweis University Budapest, Clinical Center Institute of Medicine, Department of Gastroenterology Debrecen, Department of Medicine and Gastroenterology, Markusovszky Hospital Szombathely, Department of Gastroenterology, Tolna County Teaching Hospital Szekszárd

Networks

Hungarian IBD Study Group

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Krisztina Gecse
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
15/04/2014
Actual:
15/04/2014

Study start date
Planned:
01/05/2014
Actual:
12/05/2014

Date of final study report
Planned:
31/12/2016

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Kéry Pharma, National Health Fund

Regulatory

Was the study required by a regulatory body?
No

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Drug utilisation
Effectiveness study (incl. comparative)

Main study objective:
Data on the safety and efficacy of biosimilar infliximab in clinical practice in IBD is limited so far. Therefore the aim of the present study is to conduct a prospective, nationwide, multicentre, observational cohort to examine the efficacy and safety of CT-P13 infliximab biosimilar in the induction and maintenance treatment of Crohn’s disease and ulcerative colitis.

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Intensive monitoring schemes

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name
INFLIXIMAB

Medical condition to be studied
Crohn's disease
Colitis ulcerative

Population studied

Age groups
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Estimated number of subjects
150

Study design details

Outcomes
The primary outcome of the study is early clinical remission at week 14. Clinical remission in CD was defined as a CDAI of less than 150 points or no fistula drainage according to the fistula drainage assessment. Clinical remission in UC was defined as a partial Mayo score of less than 3 points. Secondary outcomes include early clinical response at week 14, steroid-free clinical remission at week 30, sustained clinical remission and response at week 54, early and sustained biochemical response at week 14 and week 54, mucosal healing at week 54 and safety. Clinical response in CD was defined as a CDAI decrease >70 points or ?50% reduction in the number of draining fistulas.

Data analysis plan
Data appraisal and statistical analysis will be performed using the SPSS 20.0 software package. Statistical tests include calculating tests of normality, T and D tests, Chi2 test, Chi2 test with Yates' continuity correction and logistic regression.

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping
No

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
No