Observational, real-world study of INFLECTRA in patients with inflammatory bowel disease (IBD) in the United States and Canada (ONWARD)

First published: 08/02/2018

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/39469

EU PAS number

EUPAS22444

Study ID

39469

DARWIN EU® study

No

Study countries

☐ Canada

☐ United States

Study description

To describe drug use patterns, treatment adherence and associated costs in adult UC and CD cohorts treated with INFLECTRA in a real-world setting

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Multiple centres: 40 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Owens Edie

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2017

Actual: 23/02/2018

Study start date

Planned: 19/02/2018

Actual: 23/02/2018

Date of final study report

Planned: 31/10/2019

Actual: 28/01/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C1231006 PROTOCOL_Amendment 2_Pfizer_Inflectra_ONWARD_Study_25Jan2018 V3.pdf(455.7 KB)

C1231006 AMENDMENT 3 PROTOCOL VERSION 3_09SEP2020_Redacted.pdf (3.96 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The study will evaluate treatment patterns, adherence, disease activity, remission status, relapse status, treatment satisfaction, and healthcare resource utilization.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, observational study,

Study drug and medical condition

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

INFLIXIMAB

Medical condition to be studied

Inflammatory bowel disease

Colitis ulcerative

Crohn's disease

Population studied

Short description of the study population

Patients in the US and Canada initiating treatment with infliximab-dyyb for IBD.

Patients are eligible to participate if they have:
1. Initiated therapy with INFLECTRA as their first biologic;
2. Switched to INFLECTRA while in remission on a stable dose of REMICADE; or,
3. Switched to INFLECTRA from another biologic, due to non-responsiveness, intolerance, or other reasons.

Inclusion Criteria:
Patients must meet all of the following criteria to be eligible for inclusion in the study:
1. Patients with confirmed diagnosis of Ulcerative Colitis or Crohn’s Disease.
2. Evidence of a personally signed and dated informed consent document indicating that the patient has been informed of all pertinent aspects of the study.
3. Patient eligible to receive INFLECTRA for the treatment of their disease per approved drug label (patients with fistula, or stoma are eligible).

Exclusion Criteria
Patients meeting any of the following criteria will not be included in the study:
1. Patient age less than 18 years at the time of consent.

2. Patient previously failed treatment with REMICADE or INFLECTRA/CT-P13.
3. Any reported contraindications for INFLECTRA/CT-P13 or REMICADE.
4. Known hypersensitivity (including severe, acute infusion reactions) to infliximab, its excipients or other murine proteins, at the time of enrolment.
5. Patients with communication difficulties in reading or understanding the study consent or questionnaires

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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)

Special population of interest

Immunocompromised

Estimated number of subjects

300

Study design details

Outcomes

Exposure variables are limited to the dosing and timing of administration of INFLECTRA, as well as the dose and frequency of disease related concomitant medications. Outcomes variables are primarily limited to the responses from various patients reported outcomes including the Harvey-Bradshaw Index (HBI), partial MAYO score, Simplified Inflammatory Bowel Disease questionnaire (SIBDQ), To describe real world clinical and economic outcomes in adult UC and

CD cohorts who initiated therapy with INFLECTRA as their first biologic, switched to INFLECTRA from REMICADE or, switched to INFLECTRA from another biologicTo describe real world patient reported quality of life in both the UC and CD cohorts who initiated therapy with INFLECTRA as their first biologic, switched to INFLECTRA

Data analysis plan

This study will be primarily descriptive in nature. All categorical endpoints will be summarized using both the number and percentage in each category. Continuous endpoints will be summarized in the form of means, standard deviation (SD), median, interquartile ranges (IQR) and range, a 95% confidence interval (CI) for the mean will also be computed. Pearson's chi squared tests will be used for bivariate statistical testing of categorical and ordinal outcomes. Student's t tests or 1 way ANOVA will be used for comparisons of continuous outcomes. For highly skewed, non normally distributed endpoints or sample sizes under 30 in either group, non parametric Wilcoxon rank sum test will be applied. All inferences will be made assuming a two sided test with an alpha of 0.05 without adjustment for multiplicity. Approaches to controlling for baseline differences between groups such as inverse probability weights may be considered.

Documents

Study results

C1231006 NI Study Report Abstract.pdf(1.72 MB)

Study report

C1231006 NI Study Report.pdf(1.51 MB)

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