Treatment patterns and outcomes of Crohn’s disease and ulcerative colitis patients initiated with biologic therapies in Denmark (IBDBIODK)

First published: 01/05/2020

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42431

EU PAS number

EUPAS34845

Study ID

42431

DARWIN EU® study

No

Study countries

Denmark

Study description

Inflammatory bowel disease (IBD) is a chronic, autoimmune-mediated, inflammatory disorder, manifested by inflammation and tissue damage of the gastro-intestinal tract. IBD comprises two main sub-types, known as Crohn’s disease (CD), which can affect the entire digestive system and Ulcerative Colitis (UC), which mainly affects the large intestine. While biologics for CD and UC have demonstrated efficacy in clinical trials, data on their real-life use and performance remains limited. The objectives of the study are to characterize patients with CD and UC who initiate biologic therapy, and to assess outcomes and comparative effectiveness of specific biologics for CD and UC separately in a real-world setting using Danish national health registry data between 2015 and 2018. The following biologic therapies are investigated: infliximab, adalimumab, vedolizumab, ustekinumab and golimumab. The primary study outcomes are: • Discontinuation of biologic therapy. • Switch from one biologic therapy to another. The secondary outcomes are: • All-cause hospital contacts • IBD-related acute hospital contacts • IBD-related surgery • Need for corticosteroid treatment • General practitioner visits • Change in Inflammatory biomarker levels

Study status

Ongoing

Research institutions and networks

Institutions

Bispebjerg and Frederiksberg Hospital

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Institution

Center for Clinical Research and Prevention

Contact details

Study institution contact

Janne Petersen

Study contact

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Primary lead investigator

Janne Petersen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/05/2020

Study start date

Planned: 11/05/2020

Actual: 18/05/2020

Data analysis start date

Planned: 01/06/2020

Actual: 01/06/2020

Date of final study report

Planned: 31/10/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen Cilag A/S

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The primary objectives of the study are to characterize patients with CD and UC who initiate biologic therapy, and to assess outcomes and comparative effectiveness of specific biologics for CD and UC separately

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AB04) adalimumab

adalimumab

(L04AB02) infliximab

infliximab

(L04AA33) vedolizumab

vedolizumab

(L04AB06) golimumab

golimumab

(L04AC05) ustekinumab

ustekinumab

Medical condition to be studied

Colitis ulcerative

Crohn's disease

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

2300

Study design details

Outcomes

Discontinuation of biologic therapy Switch from one biologic therapy to another, • All-cause hospital contacts • IBD-related acute hospital contacts • IBD-related surgery • Need for corticosteroid treatment • General practitioner visits • Change in Inflammatory biomarker levels

Data analysis plan

The risk of the outcome will be analyzed using Cox proportional hazard regression comparing the study drugs, providing hazard ratios. Estimates are presented crude and adjusted for relevant background factors.

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

annex 5_DoIForm_v1.6_jp.pdf(120.57 KB)

Composition of steering group and observers

Research group composition.pdf(131.47 KB)

Signed code of conduct

Annex 3_Declarationofcompliance_signed.pdf(55.28 KB)

Signed code of conduct checklist

annex 2_codeofconductchecklist_signed.pdf(187.1 KB)

Signed checklist for study protocols

EUPAS34845-35081.pdf(205.86 KB)

Data sources

Data source(s)

Danish registries (access/analysis)

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