An Observational Prospective Long-term Exposure Registry of Adult Patients With Moderate-to-Severe Ulcerative Colitis (OPAL)

First published: 06/07/2016

Last updated: 22/05/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42477

EU PAS number

EUPAS13986

Study ID

42477

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Canada
- [ ] Czechia
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Korea, Republic of
- [ ] Spain
- [ ] United States

Study description

This is an observational prospective long-term exposure registry of adult participants with moderate-to-severe ulcerative colitis. Two cohorts, a Simponi-exposed cohort and a comparator cohort treated with thiopurines, will be enrolled in study. Approximately 6,000 participants are planned for enrollment, with 3,000 participants in the Simponi-exposed cohort and 3,000 participants in the comparator cohort. Participants will receive treatments in a routine clinical setting as prescribed by their physician. After enrollment, during the 10-year follow-up period, a participant may stop his or her ulcerative colitis treatment regimen and switch to a new treatment regimen. Lymphoma incidence will be primarily assessed by a questionnaire that will be sent to the investigator to obtain complete medical information about each case. An expert panel of medical specialists with extensive experience in lymphoma will be convened to validate cases of lymphoma. Besides assessing the incidence of lymphoma, long-term safety will be evaluated by capturing other adverse events of interest and serious adverse events.

Study status

Ongoing

Research institutions and networks

Institutions

Johnson & Johnson

First published: 01/02/2024

Last updated: 01/02/2024

Institution

ICON Commercialisation & Outcomes

☐ Germany

☐ Ireland

First published: 19/03/2010

Last updated: 05/07/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Caroline Kerner

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 26/02/2015

Actual: 26/02/2015

Study start date
Planned: 30/12/2016

Actual: 19/12/2016

Date of final study report
Planned: 27/08/2032

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen Biotech Inc.

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

Clinicaltrials.gov posting: NCT02808780

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective of this study is to compare the incidence of lymphoma in adult patients with moderate-to-severe ulcerative colitis who are treated with golimumab versus those treated with thiopurines

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

AZATHIOPRINE

GOLIMUMAB

MERCAPTOPURINE MONOHYDRATE

Medical condition to be studied

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

6000

Study design details

Outcomes

Incidence of Lymphoma Time Frame: 10 years Incidence was calculated as number of participants with newly diagnosed lymphoma during registry in each cohort. -Relative Risk of Lymphoma (ratio of the rate of lymphoma events in participants in each cohort) -Long-term Safety: Participants with Adverse Events of Interest (AEIs) and Serious -Clinical Disease Status as assessed by Partial

Mayo Score -SIBDQ Score -EQ-5D Score -WPAI-UC -TSQM -Health care utilization

Data analysis plan

The incidence of validated outcomes of lymphoma, rates per 100 patient-years, and the corresponding 95% CIs will be summarized and compared between the Simponi-exposed cohort and the comparator cohort. To rule out a clinically meaningful increase in the lymphoma rate in the Simponi-exposed cohort that exceeds the lymphoma rate in the thiopurine-exposed cohort, hazard ratios and 95% CIs for lymphoma will be estimated using the Cox proportional hazards regression analysis, adjusting for potential confounding variables.

Documents

Study, other information

33949_OPAL_Site List DrugDev Report_01Aug2023.pdf(122.52 KB)

OPAL General Region and Site report 24 July 2018.pdf(536.31 KB)

Primary outcome measures.pdf(95.53 KB)

Secondary outcome measures.pdf(75.16 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Exposure registry

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