An Observational European Multi-database Linkage Study to Quantify Malignancy Rates in Crohn’s Disease Patients With Complex Perianal Fistula Treated With Darvadstrocel (Alofisel-5005)

First published: 20/07/2021

Last updated: 22/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS41643

Study ID

103350

DARWIN EU® study

No

Study countries

France

Germany

Netherlands

Spain

Study description

The main aim is to learn about the risk of cancer after treatment with darvadstrocel compared to other standards of care in people with Crohn’s Disease (CD). In this study, the study doctors will review each participant’s past medical records. This study is about collecting existing information only, participants will not receive treatment or need to visit a study doctor during this study.

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Contact Takeda TrialDisclosures@takeda.com

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/06/2019

Study start date

Planned: 14/03/2023

Actual: 04/03/2023

Date of final study report

Planned: 29/10/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

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:

Primary objective of the study is to estimate the incidence rate and cumulative incidence of malignancies among crohn's disease (CD) patients with perianal fistula who received treatment with darvadstrocel or an alternative standard of care.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ALOFISEL

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

DARVADSTROCEL

Anatomical Therapeutic Chemical (ATC) code

(L04AX08) darvadstrocel

darvadstrocel

Medical condition to be studied

Crohn's disease

Anal fistula

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

5.850

Study design details

Outcomes

The primary outcomes will assess the occurrence and cumulative occurrence of malignancies in CD patients with complex perianal fistula (CPF). The secondary outcomes will assess all-cause mortality and cancer-specific mortality rate in CD participants with CPF, number of participants with anal fistula surgery, colorectal surgery, number of CD participants with CPF characterized by pharmacological therapies, and number of participants with comorbidities.

Data analysis plan

Descriptive statistics will be generated within each data source to describe baseline characteristics. Categorical variables will be summarized by frequencies and proportions, and continuous variables will be summarized by the number of valid observations, means and standard deviations, medians, and interquartile ranges, the minimum and the maximum.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Data sources will be selected from four European countries: France, Germany, Netherlands, and Spain. The selection of data sources will be dependent on the number of administrations of darvadstrocel within each country of interest.

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