

# 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

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### Study ID

103350

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### DARWIN EU® study

No

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### Study countries

☐ France

☐ Germany

☐ Netherlands

☐ Spain

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### 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.

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### 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](mailto:TrialDisclosures@takeda.com)

**Primary lead investigator**

Study Contact Takeda

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 20/06/2019

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**Study start date**

Planned: 14/03/2023

Actual: 04/03/2023

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**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

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## 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

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#### 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

**Name of medicine**

ALOFISEL

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

DARVADSTROCEL

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AX08) darvadstrocel

darvadstrocel

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**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)

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**Estimated number of subjects**

5850

## 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.

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## 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

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

**Data characterisation conducted**

No