Alofisel-5003: An Observational Post-Marketing Registry on the Effectiveness and Safety of Darvadstrocel in Patients With Crohn's Disease and Complex Perianal Fistulas (INSPIRE)

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# Administrative details

EU PAS number		
EUPAS24267		
Study ID		
45045		
DARWIN EU® study		
No		
Study countries		
Austria		
Belgium		

Czechia		
Finland		
France		
Germany		
Greece		
Hungary		
Ireland		
☐ Israel		
Italy		
Netherlands		
Norway		
Portugal		
Romania		
Slovakia		
Slovenia		
Spain		
Switzerland		
United Kingdom		

## Study description

In this study, participants with Crohn's disease with complex perianal fistulas will be treated with darvadstrocel according to their clinic's standard practice. A perianal fistula is an abnormal passageway that develops between the rectum and the skin near the anus. The fistula is considered complex if it branches into several openings or has a difficult anatomical location. The main aims of the study are to check if the fistulas are healing, the wellbeing of the participants and any side effects from the treatment.

## **Study status**

Ongoing

Research institutions and networks

## **Institutions**

# Lead Coordinating Investigator

## Charité-Universitätsmedizin

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Institution

# Maastricht University Medical Center (MUMC) Netherlands First published: 01/02/2024 Last updated: 01/02/2024 Institution Educational Institution Hospital/Clinic/Other health care facility

# University Hospital Vall d'Hebron (HUVH) Spain First published: 01/02/2024 Last updated: 01/02/2024 Institution Educational Institution Hospital/Clinic/Other health care facility

University Medical Center Utrecht (UMCU)
☐ Netherlands
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Institution Educational Institution Hospital/Clinic/Other health care facility
ENCePP partner
Radboud university medical center (Radboudumc)
Netherlands
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## Hospital Clínico Universitario Virgen de la Arrixaca

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# Hospital Universitario Virgen del Rocío

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## Hospital La Paz

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## University Medical Centre Ljubljana

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Institution

## Universitätsklinikum Schleswig-Holstein

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Utrecht, Maastricht University Medical Center, Leids Universitair Medisch Centrum, Academisch Medisch, Centrum Amsterdam, Radboud University Nijmegen Medical Centre, Universitair Medisch, Centrum Groningen, NETHERLANDS, Akershus Universitetssykehus, NORWAY, Hospital de São Teotónio, Centro Hospitalar E Universitário de Coimbra EPE, Centro Hospitalar de São João, E.P.E. Centro Hospitalar Lisboa Norte, E.P.E. -Hospital de Santa Maria, PORTUGAL, Fundeni Clinical Institute, ROMANIA, Gastroenterologicke centrum Ruzinov, SLOVAKIA, University Medical Centre Ljubljana, SLOVENIA, CHUS - H. Clinico U. de Santiago, Hospital Universitario Virgen de La Arrixaca, Hospital Universitario Miguel, Servet, Hospital Universitario de Donostia, Hospital Universitario Nuestra Sra de La Candelaria, Hospital Universitario Vall d'Hebrón - PPDS, Hospital Universitario La Paz - PPDS, Hospital

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Hospital de Montecelo, Hospital General
Universitario de Elche, SPAIN, Universitätsspital
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## Contact details

## **Study institution contact**

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Study contact

trialdisclosures@takeda.com

## **Primary lead investigator**

Study Lead

**Primary lead investigator** 

## Study timelines

### Date when funding contract was signed

Planned: 16/01/2018 Actual: 16/01/2018

#### Study start date

Planned: 31/08/2018 Actual: 14/12/2018

#### Data analysis start date

Planned: 01/01/2026

#### **Date of final study report**

Planned: 30/09/2026

# Sources of funding

Pharmaceutical company and other private sector

## More details on funding

Takeda

# 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:

Non-interventional study

#### Scope of the study:

Effectiveness study (incl. comparative)

## Main study objective:

The primary objective of the study is to evaluate the real-world clinical effectiveness and safety of darvadstrocel in patients with Crohn's disease (CD) with complex perianal fistulas for a duration of 36 months with the primary evaluation at six months.

# Study Design

#### Non-interventional study design

Other

#### Non-interventional study design, other

Registry study

# Study drug and medical condition

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

#### Medical condition to be studied

Anal fistula

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**

800

# Study design details

#### **Outcomes**

The primary outcomes are clinical response and clinical remission. Clinical response is defined as a reduction of at least 50 percent (%) in the number of draining perianal fistula treated with darvadstrocel compared to baseline. Clinical remission is defined as a reduction of all draining perianal fistulae treated with darvadstrocel compared to baseline. The secondary outcomes includes evaluation of combined remission, relapse of perianal fistula and new perianal abscess fistula treated with darvadstrocel, surgical procedures and post-surgery complication status, and clinical/patient assessment of disease activity using subcomponent symptom scores from the Perianal Disease Activity Index (PDAI) and Harvey-Bradshaw Index (HBI).

#### Data analysis plan

The analysis will be basically descriptive. Continuous variables will be described by mean, standard deviation (SD), median, interquartile range (IQR), minimum, maximum, number of known and number of unknown observations. When relevant, 2-sided 95% confidence intervals (CI) will be provided. Categorical

variables will be described by frequency and percentages (n, %). Percentages will be calculated using the most appropriate denominator, in some cases missing data will be included as a separate category depending on the nature of the variable. In all tables with percentages, the denominator will be reported. Subgroup presentations of the outcomes in terms of continuous and categorical variables and survival curves will be provided as appropriate.

## 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

Prospective patient-based data collection, Baseline clinical and treatment information, and effectiveness and safety data (including magnetic resonance imaging MRI reports) will be collected retrospectively, up until the date of entry into the registry, when a patient has been treated before the registry is available to them or prior to consent, but consent has since been provided for participation.

# 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