

# Alofisel-4001: Postauthorization Safety Study of the Long-Term Safety and Efficacy of Repeat Administration of Darvadstrocel in Patients With Crohn's Disease and Complex Perianal Fistula

**First published:** 07/10/2019

**Last updated:** 31/10/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS31439

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### Study ID

44182


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### DARWIN EU® study

No

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### Study countries

 Austria

 Czechia

 France

 Germany

 Israel

 Spain

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## Study description

The main aim is to check the long-term side effects of a repeat treatment of darvadstrocel and to see if that treatment improves symptoms of Crohn's disease and complex perianal fistula.

Participants will attend 8 clinic visits and will receive 1 treatment of darvadstrocel at the third visit. An magnetic resonance imaging (MRI) will be performed several times during the study.

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## Study status

Finalised

# 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: 22/05/2019

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### **Study start date**

Planned: 15/01/2021

Actual: 22/12/2020

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### **Data analysis start date**

Planned: 22/05/2025

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

Planned: 30/09/2025

Actual: 27/08/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda

## Study protocol

[Alofisel-4001-clinical-study-protocol-redact.pdf](#) (2.08 MB)

[Alofisel-4001-clinical-study-protocol-redact.pdf](#) (1.39 MB)

## 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 topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Clinical trial

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**Scope of the study:**

Safety study (incl. comparative)

**Main study objective:**

To evaluate the long-term safety of repeat administration of darvadstrocel in subjects with CD and complex perianal fistula by evaluation of adverse events (AEs), serious adverse events (SAEs), adverse events of special interest (AESIs), and pregnancy.

## Study Design

**Clinical trial randomisation**

Non-randomised clinical trial

## Study drug and medical condition

**Medicinal product name**

[ALOFISEL](#)

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

DARVADSTROCEL

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**Medical condition to be studied**

### **Additional medical condition(s)**

Complex Perianal 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**

50

## Study design details

### **Outcomes**

Primary outcomes of the study are assessments of safety parameters through treatment-emergent adverse events (TEAEs), TE serious AEs, Pregnancy, TEAE of special interests- (Immunogenicity/alloimmune reactions, Hypersensitivity, Transmission of infectious agents, Tumorigenicity (applying to malignant tumors only), Ectopic tissue formation, Medication errors), Secondary outcomes included combined remission, clinical remission, clinical response, relapse and time to relapse, new perianal abscess and Change in scores of discharge and pain items of Perianal Disease Activity Index (PDAI) score after darvadstrocel

repeat administration.

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### **Data analysis plan**

Count and percentage of participants with AEs, SAEs and AESIs will be summarized by system organ class and preferred term using MedDRA terminology for the overall study population and for relevant subgroups. All efficacy outcomes will be summarized by visit, as applicable. Proportion of participants with each of following outcomes, along with 95% 2-sided confidence intervals will be provided by visit: 1) Clinical remission, 2) Clinical response, 3) Combined remission, 4) Reopening of any of the treated external openings with active drainage, 5) New perianal abscess in treated fistula. In addition, at Weeks 24, 52, 104, and 156, the proportion of participants who changed in status since the previous assessment will be provided. Change from baseline in PDAI discharge and pain subscores will be summarized descriptively by visit. Among participants who achieve combined probability of relapse across time will be estimated using Kaplan-Meier estimator.

## Documents

### **Study report**

[Alofisel-4001-clinical-study-report-redact.pdf](#) (822.35 KB)

## 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

Prospective patient-based data collection

## 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