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

First published: 17/09/2018

Last updated: 19/11/2025

Study | Finalised

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

Finalised

Research institutions and networks

Institutions

Lead Coordinating Investigator

Charité-Universitätsmedizin

First published: 01/02/2024

Last updated: 01/02/2024

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

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

University Medical Center Utrecht (UMCU)

Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Radboud university medical center (Radboudumc)

Netherlands

First published: 30/06/2022

Last updated: 21/03/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Hospital Universitario Virgen Macarena

Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Hospital Clínico Universitario Virgen de la Arrixaca

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Hospital Universitario Virgen del Rocío

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Hospital La Paz

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University Medical Centre Ljubljana

First published: 01/02/2024

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Institution

Universitätsklinikum Schleswig-Holstein

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Institution

Medical University of Innsbruck

Austria

First published: 19/11/2025

Last updated: 19/11/2025

Institution

Hospital/Clinic/Other health care facility

Allgemeines Krankenhaus der Stadt Wien, Krankenanstalt Rudolfstiftung, Ordensklinikum Elisabethinen, AUSTRIA, UZ Leuven, UZ Gent, BELGIUM, Clinical Hospital Sestre Milosrdnice, CROATIA Nemocnice Horovice a.s, Czech Republic, Tampereen yliopistollinen sairaala, Jorvi Hospital, FINLAND, Hôpital de la Croix Saint-Simon, CHRU Lille, Hôpital Pontchaillou, Centre Hospitalier Lyon

Sud, Hôpital Beaujon, Fondation Hôpital Saint Joseph, FRANCE, Universitätsklinikum, Carl Gustav Carus an der TU Dresden, St. Josefs-Hospital Wiesbaden GmbH, Städtisches Klinikum Lüneburg, Universitatsklinikum Munster, Kliniken Essen Mitte, Isar Kliniken GmbH, Universitatsklinikum Schleswig-Holstein, Charité -, Universitätsmedizin, Berlin, Verein Krankenhaus Waldfriede Ev, GERMANY, Aretaieio Hospital of Athens, GREECE, Szegedi Tudomanyegyetem Szent-Gyorgyi Albert Klinikai Kozpont, Magyar Honvédség Egészségügyi Központ, HUNGARY, St Vincent's University Hospital, University Hospital Galway, IRELAND, Hadassah Medical Center – PPDS, Rabin Medical Center – PPDS, Meir Medical Center, Sheba Medical Center – PPDS, Tel Aviv Sourasky Medical Center PPDS, Edith Wolfson Medical Center, ISREAL, ASST Fatebenefratelli Sacco, Ospedale Luigi Sacco - INCIPIT – – PIN, Azienda Ospedaliero

Universitaria Di Bologna - Policlinico S Orsola Malpighi, Fondazione Policlinico Universitario A Gemelli, Azienda Ospedaliera Ospedali Riuniti Villa Sofia- Cervello, Azienda Ospedaliera Universitaria Federico II, ITALY, Universitair Medisch Centrum 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 Clinico Universitario de Valencia, Hospital Universitario Virgen del Rocio – PPDS, Hospital Universitario Fundacion Jimenez Diaz, Hospital Universitari i Politecnic La Fe de Valencia, Hospital Clinic de Barcelona, Hospital Universitario Virgen Macarena, Complejo Hospitalario, de Navarra, Hospital de Montecelo, Hospital General Universitario de Elche, SPAIN, Universitätsspital Zürich, Centre Hospitalier Universitaire Vaudois, Gastroentérologie Beaulieu SA, SWITZERLAND, Royal Hallamshire Hospital, St Mark's Hospital, UK

Contact details

Study institution contact

Genestin Elisabeth trialdisclosures@takeda.com

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

Actual: 23/12/2024

Date of final study report

Planned: 30/09/2026

Actual: 24/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Alofisel-5003-clinical-study-protocol-redact1.pdf (8.75 MB)

Alofisel-5003-clinical-study-protocol-redact.pdf (4.18 MB)

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

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

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.

Documents

Study results

Alofisel-5003-clinical-study-report-redact.pdf (731.59 KB)

Data management

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