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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Last updated: 16/02/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/45045

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 institution and networks

Institutions

Lead Coordinating Investigator

Charité-Universitätsmedizin
First published: 01/02/2024
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Institution

Maastricht University Medical Center (MUMC)
Netherlands
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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
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Institution

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

Hospital Universitario Virgen Macarena

Spain
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Institution

Educational Institution

Hospital/Clinic/Other health care facility

Hospital Clínico Universitario Virgen de la Arrixaca

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Institution

Hospital Universitario Virgen del Rocío

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Hospital La Paz
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Universitätsklinikum Schleswig-Holstein
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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
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Study contact

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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

Study type list

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

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