

INSPECT: A retrospective chart review study evaluating the longer-term effectiveness of darvadstrocel in patients who completed ADMIRE-CD

First published: 22/03/2019

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Study

Finalised

Administrative details

EU PAS number

EUPAS27731


Study ID

42062

DARWIN EU® study

No


Study countries

 Austria


 Belgium

 France

 Germany

 Israel

 Italy

 Netherlands

 Spain

Study description

This is a multi-site, retrospective chart review study of patients with Crohn's disease (CD), who received darvadstrocel or placebo and completed at least 52 weeks of follow-up in the 'Adipose Derived Mesenchymal Stem Cell for Induction of Remission in Perianal Fistulising Crohn's Disease (ADMIRE-CD)' clinical trial. This study will review patients' medical records to collect additional longer-term data over a period of 104 weeks post-trial completion for all patients who completed at least 52 weeks of follow up within the ADMIRE-CD trial. The study objectives are to evaluate the following over 52 weeks (1 year) and 104 weeks (2 years) post-trial completion: the time in remission and the proportion of patients who sustained remission, the incidence of ADMIRE-CD treated fistula relapse, the proportion of patients with new fistula occurrence, and the response, remission and relapse status of new onset fistula, changes in perianal and luminal disease activity, biologic and non-biologic medical treatment patterns, surgical and non-surgical procedures and healthcare resource utilisation (HRU), and the incidence of adverse events of special interest (AESIs). The data is anticipated to be collected between March 2019 and August 2019. The study aims to enroll as many as possible of the 131 patients who completed at least 52 weeks of follow up within the ADMIRE-CD trial. The study will be conducted at a maximum of 25 sites in 8 countries (Austria, Belgium, France, Germany, Israel, Italy, Netherlands, and Spain). As part of this study, new data will only be collected from the chart review study period (with the exception of some specific prior fistula history data which was not collected during ADMIRE-CD). No additional data from the ADMIRE-CD study period will be

collected. The analysis for this study will therefore leverage previously collected and analysed trial data.

Study status

Finalised

Research institutions and networks

Institutions

A.ö. Krankenhaus der Barmherzigen Brüder,
Medizinische Universität Wien Austria, Shaare
Zedek Medical Center, Tel Aviv Sourasky Medical
Center, Rambam Health Corporation, Chaim Sheba
Medical Center Israel, Hospital Universitario La
Paz, Hospital Clinic de Barcelona, Hospital General
Juan Ramon Jimenez, Hospital Universitario Virgen
del Rocio, Hospital Universitario Fundacion
Jimenez Diaz, Hospital Provincial de Pontevedra
Spain, Hospital Universitario 12 de Octubre,
Hospital Clinico San Carlos, Hospital Universitario
Ramon y Cajal, Hospital Universitario de La
Princesa, Hospital de Manises Spain, VU Medisch

Centrum, Academisch Medisch Centrum
Amsterdam Netherland, CHRU Lille, Hopital Cote
de Nacre, CHU Amiens Picardie- Hôpital Nord,
Hopital Nord AP-HM, Groupe Hospitalier Archet I Et
II France, H.-Hartziekenhuis Roeselare-Menen vzw,
UZ Gent, Universitair Ziekenhuis Belgium, Azienda
Ospedaliera Di Padova, Complesso Integrato
Columbus, Istituto Clinico Humanitas, AOU
dell'Università degli Studi della Campania Luigi
Vanvitelli Italy, Städtisches Klinikum Lüneburg,
Evangelisches Krankenhaus Kalk gGmbH
Germany, C.H. Regional Reina Sofia, Hospital de
Sagunto Y C.E. Hospital Universitario Son Espases
Spain

Contact details

Study institution contact

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Study contact

Primary lead investigator

Julián Panés

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2018

Actual: 01/10/2018

Study start date

Planned: 04/04/2019

Actual: 03/07/2019

Data analysis start date

Planned: 30/11/2019

Actual: 22/01/2020

Date of interim report, if expected

Planned: 31/01/2020

Date of final study report

Planned: 29/04/2020

Actual: 17/07/2020

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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To evaluate the following over 52 and 104 weeks post-trial completion: time in remission and proportion of patients who sustained remission, incidence of relapse, new fistula occurrence and response, remission and relapse status of new onset fistula, disease activity, medical treatment patterns, surgical and non-surgical procedures and healthcare resource use, AESIs.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multi-centre, retrospective chart review study

Study drug and medical condition

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

DARVADSTROCEL

Medical condition to be studied

Crohn's disease

Anal fistula

Population studied

Short description of the study population

Patients with Crohn's disease (CD), who received darvadstrocel or placebo and completed at least 52 weeks of follow-up in the 'Adipose Derived Mesenchymal Stem Cell for Induction of Remission in Perianal Fistulising Crohn's Disease (ADMIRE-CD)' clinical trial.

Patients were excluded if they did not provide informed consent or if there was no information on patient care within the 104 weeks INSPECT study period.

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)
-

Special population of interest

Immunocompromised

Estimated number of subjects

131

Study design details

Outcomes

The primary outcomes include clinical response, clinical remission, perianal abscess, rescue medication for perianal fistulising disease, relapse of perianal fistula, development of new perianal fistula, perianal and luminal disease activity, treatment patterns, surgical and non-surgical procedures, medical

healthcare resource utilization and AESIs.

Data analysis plan

A statistical analysis plan will be finalized prior to any data analyses being performed defining all analytic populations and definitions of derived variables. Analyses will be reported in descriptive manner and compare outcomes between study arms (darvadstrocel versus control). Data from the trial will not be re-analysed and will be directly integrated from clinical trial datasets. Variables from medical records will be collected to assess outcomes during 104-weeks chart review study period. Continuous data will be described by mean, standard deviation, median, interquartile range, minimum, maximum, and number of unknown/missing observations and categorical variables will be described by frequency and percentages (when applicable, 2-sided 95 % confidence interval CI will be provided). Time-to-event data will be analysed using survival analysis techniques. Regression will be used to analyse potential predictors of and/or variables associated with response and remission.

Documents

Study results

[Alofisel-5004_09Oct20_UEGW2020_INSPECT_redacted.pdf](#) (1.25 MB)

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

Retrospective medical chart review

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