A drug utilisation study (DUS) of the use of oral fidaxomicin in the routine clinical setting (2819-CL- 2002) (Anemone)

First published: 26/06/2015

Last updated: 12/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS9507

Study ID

20087

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

Study description

Patients with inflammatory bowel disease, fulminant or life threatening Clostridium difficile infection were excluded from the fidaxomicin clinical programs. Data on patients with renal or hepatic impairment and pregnant patients are limited. In order to fill this gap, the sponsor has proposed a retrospective, observational, multicentre drug utilisation study conducted in Europe based on secondary use of data derived from medical records.The objective of this drug utilisation study is to further assess the use of fidaxomicin in standard clinical practice and to collect information on patient use in reallife conditions, notably estimating the proportion of patients with a medical condition of specific interest among patients treated with fidaxomicin.Adult patients with a fidaxomicin prescription between the launch of the product and the date when the first site was contacted in a country are eligible for the study. Patients enrolled in a clinical trial involving fidaxomicin will not be considered for participation in the study.

Study status

Finalised

Research institutions and networks

Institutions

Real World & Late Phase Research (RWLPR), Quintiles

France

First published: 20/03/2015

Last updated: 20/08/2024

Institution | Other

Real World Solutions, IQVIA

☐ Netherlands

☐ United Kingdom (Northern Ireland)

First published: 28/04/2011

Last updated: 22/03/2024

Institution | Other | ENCePP partner

Multiple centres: 22 centres are involved in the study

Networks

NIHR Medicines for Children Research Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

Department Clinical Trial Registration
Clinicaltrialregistration@astellas.com

Study contact

Clinicaltrialregistration@astellas.com

Primary lead investigator

Maria Vehreschild

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 27/02/2015

Study start date
Actual: 23/10/2015

Data analysis start date
Actual: 19/10/2016

Date of final study report
Actual: 22/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe BV

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Protocol ID number: 2819-CL-2002

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The objective of this drug utilisation study is to furtherassess the use of fidaxomicin in standard clinicalpractice and to collect information on patient use in reallife conditions. Demographic and clinical data, includingmedical and treatment background, will be collected.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-authorisation, retrospective chart review

Study drug and medical condition

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

FIDAXOMICIN

Medical condition to be studied

Inflammatory bowel disease

Clostridium difficile infection

Renal impairment

Hepatic function abnormal

Pregnancy

Population studied

Short description of the study population

Patients aged ≥ 18 years for whom the time of prescription of fidaxomicin and their entire corresponding observational period fell within the (country-specific) eligibility 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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

512

Study design details

Outcomes

To estimate the proportion of patients with a medical condition ofspecific interest (i.e. IBD, fulminant or life threatening CDI, moderate or severe hepatic impairment, renal impairment, pregnancy) of the total study population treated with fidaxomicin. To collect information of the use of fidaxomicin in routine clinical setting (indication, dose and duration of use) and to further assess safety characteristics (i.e. the events of death, and laboratory and electrocardiogram ECG results on specific timepoints) in patientspopulations with medical conditions of specific interest and in the overall population.

Data analysis plan

All data for the subjects who meet the entry criteria will be summarized.Continuous variables will be summarized using descriptive statistics (mean, standard deviation, median, minimum, maximum), categorical variables will be summarized using frequency tabulationspresenting frequency and percentage (based on non-missing responses) in each category.

Documents

Study results

2819-cl-2002-clrr-02-disc02-en-final-02_redacted abstract.pdf(148.46 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)

Drug dispensing/prescription data

Other

Data sources (types), other

Medicals Records

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

Unknown