A Multicenter, Multinational, Observational Study to Collect Information on Safety and to Document the Drug Utilization of Fampyra® When Used In Routine Medical Practice (LIBERATE)

First published: 29/03/2019

Last updated: 14/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/32511

EU PAS number

EUPAS28367

Study ID

32511

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Canada
- [ ] Czechia
- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] Israel
- [ ] Lebanon
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] United Arab Emirates

Study description

The primary objective of the study is to collect additional safety data including the incidence rate of seizure and other specific Adverse Events (AEs) of interest from participants taking Fampyra in routine clinical practice. The secondary objectives of this study are to characterize utilization patterns of Fampyra in routine clinical practice, to assess the effectiveness of risk minimization measures as described in the risk management plan for Fampyra, to assess the change over time in participant self-reported evaluation of the physical and psychological impact of Multiple Sclerosis (MS) while taking Fampyra and to assess the change over time in physician assessment of walking ability in participants taking Fampyra (MS participants only).

Study status

Finalised

Research institutions and networks

Institutions

Biogen

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Institution

Multiple centres: 168 centres are involved in the study

Contact details

Study institution contact

Study Director Biogen

Study contact

ctrr@biogen.com

Primary lead investigator

Study Director Biogen

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 07/07/2011

Study start date
Actual: 16/04/2012

Date of final study report
Planned: 08/11/2019

Actual: 05/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

Study protocol

218MS401 Protocol V3 FINAL 24Feb14_Redacted.pdf(1.32 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

218MS401NCT01480063

https://clinicaltrials.gov/ct2/show/NCT01480063?term=218ms401&rank=1

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The primary objective of the study is to collect additional safety data including the incidence rate of seizure and other specific Adverse Events (AEs) of interest from participants taking Fampyra in routine clinical practice.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, observational study

Study drug and medical condition

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

FAMPRIDINE

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

To be eligible to participate in this observational study, patients must fulfil the following eligibility criteria at the time of Enrollment:
1. Patients who have been newly prescribed Fampyra according to the terms of the marketing authorization, but who have not yet started treatment with Fampyra.
2. Patients who are willing and able to provide written informed consent.

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

4734

Study design details

Outcomes

• Number of Participants with Adverse Events, • Utilization patterns of Fampyra in Routine Clinical Practice• Effectiveness of risk minimization measures• Change from Baseline in Physician’s Clinical Global Impression of Improvement (CGI-I) of Walking Ability• Participants’ Assessment of Physical and Psychological Impact of Multiple Sclerosis Using the Multiple Sclerosis Impact Scale-29 Items (MSIS-29)

Data analysis plan

Statistical analyses will be exploratory and descriptive in nature.

Documents

Study results

218MS401_EUPASResultsPacket_Redacted.pdf(288.83 KB)

Data management

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No