European multicenter retrospective-prospective cohort study to observe Safinamide safety profile and pattern of use in clinical practice during the first post-commercialization phase - Study Z7219N02 (SYNAPSES)

First published: 09/06/2016

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13745

Study ID

41165

DARWIN EU® study

No

Study countries

Belgium
Germany
Italy
Spain
Switzerland
United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Zambon

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Institution

Multiple centres: 128 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Carlo Cattaneo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/12/2015

Actual: 27/04/2016

Study start date

Planned: 30/06/2016

Actual: 04/08/2016

Date of final study report

Planned: 31/10/2019

Actual: 06/02/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Zambon SpA

Study protocol

SYNAPSES_Stuy protocol_signed_FINALISSIMO.pdf (1.24 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To observe Safinamide safety profile and pattern of use in clinical practice during the first post-commercialization phase.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

SAFINAMIDE METHANESULFONATE

Medical condition to be studied

Parkinson's disease

Population studied

Short description of the study population

Adult patients treated with Safinamide according to clinical practice will be consecutively enrolled in each participating site during the 24-month recruitment period.

Inclusion criteria (at enrolment visit):
1. Adult male and female patients (≥18 years).
2. Patients who start treatment with Safinamide at enrolment visit or who started it in the previous 4 months, according to clinical practice after its commercialization. This is an observational study, hence physician’s decision of starting treatment with Safinamide has been taken before the patient inclusion in the study and is completely independent from the study protocol.
3. Patients who have signed informed and privacy form consent according to local legal requirement.

Exclusion criteria (at enrolment visit):
1. Patients participating in any clinical trial on Safinamide at study inclusion

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

Other

Special population of interest, other

Parkinson's disease patients

Estimated number of subjects

1.600

Study design details

Outcomes

To describe the occurrence of adverse events in patients treated with Safinamide in real-life conditions during 1 year in the first post-commercialization phase as reported by the Investigators. To describe the characteristics of patients treated with Safinamide according to clinical practice (demographics, disease duration, disease severity, previous treatment for PD, concomitant relevant conditions with particular focus on psychiatric ones and related treatments).To describe Safinamide treatment patterns in real-life setting (treatment duration, dose adjustments and interruptions.

Data analysis plan

Data will be described on all enrolled patients fulfilling inclusion/ exclusion criteria.Patients with missing values will not be excluded from the analysis, but their data will not be replaced, frequency of missing data will be given for all analyzed variables.The aim of the study is merely descriptive and there are no pre-specified hypotheses.Categorical variables will be described by means of absolute and relative frequencies, while continuous variables by means of mean, standard deviation, quartiles, min and max.

Documents

Study results

SYNAPSES_FinalStudyReport_v1.5.pdf (2.62 MB)

SYNAPSES_FinalStudyReport_v1.6_clean.pdf (2.69 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

Prospective patient-based data collection, Retrospective patient-based data collection (medical charts).

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