AN OBSERVATIONAL, PROSPECTIVE, MULTINATIONAL, MULTICENTRE STUDY COMPARING THE EFFECTIVENESS OF SAFINAMIDE, RASAGILINE AND OTHER “STANDARD OF CARE” AS ADD-ON THERAPY TO LEVODOPA (L-DOPA) IN PARKINSON’S DISEASE (PD) FLUCTUATING PATIENTS (SUCCESS)

First published: 25/05/2021

Last updated: 30/10/2023

Study Ongoing

Administrative details

EU PAS number

EUPAS41248

Study ID

41249

DARWIN EU® study

No

Study countries

Belgium

Germany

Italy

Spain

United Kingdom

Study description

This is an observational, prospective, multinational, multicentre study. Adult patients treated with safinamide, rasagiline or other SoC medications according to clinical practice and meeting the inclusion/exclusion criteria will be consecutively enrolled in each participating site. Study participation will be up to a maximum duration of approximately 12 months and will comprise three visits: a baseline visit at the start of the observation period, a second visit, approximately 6-months later, and a final visit at the end of the observation period (approximately at 12 months). No visits or examinations, laboratory tests or procedures are mandated as part of this study. The visits will take place during routine clinical practice. During the study, patients may continue or change the treatment based on their physician’s medical judgement. The primary objective is to evaluate how safinamide, rasagiline and other SoC drugs are associated with the quality of life of PD patients by means of the Parkinson’s Disease Questionnaire (PDQ)-39 items.

Study status

Ongoing

Research institutions and networks

Institutions

Zambon

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Institution

Contact details

Study institution contact

Carlo Cattaneo carlo.cattaneo@zambongroup.com

Study contact

carlo.cattaneo@zambongroup.com

Primary lead investigator

Carlo Cattaneo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/09/2019

Actual: 04/10/2019

Study start date

Planned: 02/12/2019

Actual: 05/12/2019

Date of final study report
Planned: 30/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Zambon S.p.A.

Study protocol

CLEAN SUCCESS OBSERVATIONAL PROTOCOL FINAL VERSION 2.0_21 JUNE 2019 Signed.pdf (612.93 KB)

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:

To evaluate how safinamide, rasagiline and other SoC drugs are associated with the quality of life of PD patients by means of the Parkinson’s Disease Questionnaire (PDQ)-39 items.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This is an observational, prospective, multinational, multicentre study.

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

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

1235

Study design details

Outcomes

The change from baseline to the end of study (12 months) in the PDQ-39 total score. • The change from baseline to 6 months in the PDQ-39 total score. • The change from baseline to 6 months and to the end of study (12 months) in the PDQ-39 sub-scores (domains and single items). • The change from baseline to 6 months and to the end of study (12 months) in the UPDRS III score. • The change from baseline to 6 months and to the end of study (12 months) in the NRS.

Data analysis plan

The primary objective of the study is to evaluate the change from baseline to the end of the study (12 months) in the PDQ-39 total score. Because the treatments will not be randomly assigned to patients, potential confounding and selection biases will be addressed by developing a propensity score for each of the treatment in study (considering other SoC as a single group), using multinomial logistic regression with study treatment as dependent variable and a set of selected covariates (confounders) as independent variables. The

propensity score calculated from the logistic analysis for each patient represents the probability that a patient would be treated with safinamide rather than with rasagiline, rather than with other SoC. The calculated propensity scores will be then used to compute weights for a weighted outcome analysis.

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

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