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





### Administrative details

**EU PAS number** 

**EUPAS41248** 

Study ID

41249

**DARWIN EU® study** 

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

First published: 01/02/2024

**Last updated:** 01/02/2024

Institution

### Contact details

#### **Study institution contact**

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### **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 stability**

**Check conformance** 

Unknown

### **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No