A prospective observational study to evaluate the clinical outcomes and burden of disease of PD patients with motor fluctuations not adequately controlled by current PD medications (PROSPECT)

First published: 29/09/2020

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Study Ongoing

Administrative details

EU PAS number

EUPAS36303

Study ID

40298

DARWIN EU® study

No

Study countries

Australia

Canada

France

Japan

Spain

United Kingdom

United States

Study description

This is a prospective, multi-country, observational study evaluating the disease progression of advanced Parkinson's Disease (PD) patients experiencing motor fluctuations not adequately controlled by current PD medications.

Study status

Ongoing

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/04/2020

Actual: 16/04/2020

Study start date
Planned: 30/09/2020

Actual: 17/11/2020

Date of final study report
Planned: 30/07/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

H20-012 PROSPECT Protocol synopsis_16Apr2020_Final.pdf (417.6 KB)

H20-012 PROSPECT_Protocol_Amendment 3.0_Synopsis.pdf (217.06 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

H20-012

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

The objective of this observational study is to describe the clinical outcomes and disease burden of advancing PD disease in PD patients with motor fluctuations no longer controlled by current PD medications.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective observational study

Study drug and medical condition

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

550

Study design details

Outcomes

Change of Off time from baseline to 24 months as measured by PD diary. Change in Off time from baseline to 12 monthsChange in dyskinesia from baseline to 12 and 24 monthsChange in HY Stage (in ON and OFF state) from baseline to 12 and 24 monthsChange in EQ5D5L patient and caregiver Total score from baseline to 12 and 24 monthsChange in MDS UPDRS part II score from baseline to 12 and 24 monthsChange in NMSS Total score from baseline to

12 and 24 months

Data analysis plan

Descriptive statistics will be used to summarize all endpoints. Continuous endpoints will be summarized using number of missing and non-missing observations, mean, median, minimum, maximum, standard deviation and 95% confidence interval. Categorical values will be summarized as the number of patients and percentages (%) of patients in each category.

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