Advanced Parkinson’s disease treatment eligibility in France: an epidemiological study (EPIPARK)

First published: 26/09/2017

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Study Finalised

Administrative details

EU PAS number

EUPAS20918

Study ID

31124

DARWIN EU® study

No

Study countries

France

Study description

This is an epidemiological, cross-sectional, descriptive, non-interventional, and multicenter study designed to estimate, in Metropolitan France, the size of the population of PD patients eligible for Duodopa®, in accordance with the conditions defined by the French Authority for Health in its Transparency Committee’s opinion. Two complementary parts will be done simultaneously: a CENSUS and a descriptive CORE part.

Study status

Finalised

Research institutions and networks

Institutions

NA

Multiple centres: 38 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Clinical Trial Disclosure Abbvie

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/06/2017

Study start date

Actual: 26/07/2017

Data analysis start date

Planned: 27/07/2018

Actual: 20/09/2018

Date of final study report

Planned: 05/07/2019

Actual: 29/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

11262-synopsis_Redacted.pdf (131.75 KB)

EPIPARK_Protocol_v1.0_Redacted.pdf (1.3 MB)

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

H18-162

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

The main objective of this study is to estimate, in Metropolitan France, the size of the population of Parkinson’s disease patients eligible to Duodopa® in accordance with the conditions defined by the French Authority for Health in its Transparency Committee’s opinion.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Parkinson's disease

Population studied

Short description of the study population

Parkinson's disease (PD) patients at advanced stage of disease (or their legal representatives), who have received verbal and written information about the study.

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

442

Study design details

Outcomes

-Number and percentage of patients not eligible for Deep Brain Stimulation -Number and percentage of patients presenting contra-indication, intolerance or failure to subcutaneous apomorphine continuous infusion -Number and percentage of patients without contra-indications and precautions for Duodopa® use as they are defined in the drug SmPC (ANSM, Duodopa®), -To estimate, in Metropolitan France, the size of the population of PD patients

eligible for Duodopa® according to the indication defined by its marketing authorization -To describe advanced PD patients and disease characteristics (including background history) -To estimate the proportion of PD patients eligible for each invasive therapy (Deep Brain Stimulation, Apomorphine or Duodopa®)

Data analysis plan

1. Descriptive analysis of patients data :-quantitative variables (sample size (data provided, missing values), mean, standard deviation, median, mode if relevant, first and third quartiles and range. If relevant, 95% confidence interval (CI) will be presented.-qualitative variables : number of non-missing values, number of missing values, frequency and percentage per modality. Note that missing values will be excluded from the calculation of percentages, unless their proportion is important (i.e. >10%). If relevant, 95% CI of the proportion will be presented2. Statistical adjustments to correct for:-potential duplicates, -incompleteness of the census, -non-inclusion of eligible patients3. Statistical extrapolations to ensure generalizability.

Documents

Study results

EPIPARK_CSR Abstract_final.pdf (116.72 KB)

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

Unknown