Risk of Melanoma Among Parkinson's Disease Patients (TV1030-CNS-50024)

First published: 23/07/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS19909

Study ID

42749

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is a retrospective cohort study to evaluate the risk of malignant melanoma in individuals with Parkinson's disease treated and not treated with rasagiline. The study will be implemented in the United States Medicare research

database, using data from 2006 through 2015 among individuals aged 65 years or older. The study is designed to estimate the incidence rate of melanoma in new users of rasagiline (Cohort A), new users of other anti-Parkinson's medications (Cohort B), new and prevalent users of other anti-Parkinson's medications (Cohort C), and individuals without Parkinson's disease (Cohort D). Melanoma incidence will be compared between Cohorts A and B, A and C, and C and D. Potential outcomes of melanoma identified in the claims database will be validated through review of medical records.

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- ☐ France
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom
- ☐ United Kingdom (Northern Ireland)
- ☐ United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution **Not-for-profit** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Johannes Catherine

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/03/2017

Actual: 10/03/2017

Study start date

Planned: 30/07/2017

Actual: 08/01/2018

Date of final study report

Planned: 21/10/2019

Actual: 31/10/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva Pharmaceutical LTD

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To estimate and compare the incidence rate of melanoma PD patients who start treatment with rasagiline and those who start treatment with other anti-Parkinson’s drugs. To examine the association between use of rasagiline and malignant melanoma among PD patients. To estimate and compare the incidence rate of melanoma in PD patients not treated with rasagiline and the rate in subjects without PD.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N04BD02) rasagiline

rasagiline

Medical condition to be studied

Parkinson's disease

Population studied

Short description of the study population

The study population comprised adults aged ≥65 years with diagnosis claims for PD and continuous enrollment for ≥6 months in Medicare Parts A, B, and D fee-for-service coverage who started rasagiline (Cohort A) or a non-rasagiline APD (Cohort B) in 2006- 2015.

Age groups

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

Patients with Parkinson's disease

Estimated number of subjects

300000

Study design details

Outcomes

melanoma

Data analysis plan

Descriptive analyses will compare baseline characteristics of the study cohorts and describe the patterns of anti-Parkinson’s medication use. The incidence of melanoma will be estimated in all cohorts using both validated cases and possible cases for whom medical record information is not available. Incidence

rate ratios will be calculated and stratified by relevant confounding variables for each exposure group comparison. Hazard ratios will be estimated using Cox proportional hazards models for each exposure group comparison, with adjustment for covariates. Sensitivity analyses will be performed to evaluate potential detection bias to determine whether rasagiline users may be screened more intensively for melanoma than users of other medications, including the comparison of incidence rates of non-melanoma skin cancer between rasagiline users and users of other anti-Parkinson's medications.

Documents

Study report

0303432_ICPE_Abstract_Main results_09Feb2021_final for submission.pdf(81.46 KB)

Study, other information

0303432_ICPE2021_Rasagiline and Melanoma_Final_11Aug2021.pdf(164.75 KB)
0303432_ICPE2021_Validation_Saltus_Final_11Aug2021.pdf(158.93 KB)
0303432_ICPE_Abstract_Validation_Rev Dec 2020_clean.pdf(127.58 KB)

Study publications

Johannes CB, Saltus CW, Kaye JA, Calingaert B, Kaplan S, Gordon MF, Andrews EB…
Saltus CW, Kaplan S, Gordon MF, Calingaert B, Andrews EB, Kaye JA, Johannes CB…

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)

Administrative healthcare records (e.g., claims)

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