Risk of Mortality Associated With Pimavanserin Use Compared With Other Atypical Antipsychotics in Patients With Parkinson’s Disease–Related Psychosis

First published: 21/03/2022

Last updated: 22/09/2025

Study Finalised

Administrative details

EU PAS number

EUPAS46331

Study ID

50226

DARWIN EU® study

No

Study countries

United States

Study description

Pimavanserin is approved in the United States (US) for the treatment of hallucinations and delusions associated with Parkinson’s disease psychosis (PDP).
The main objective of this study is to compare the risk of mortality among patients with PDP after initiation of pimavanserin with the risk of mortality after initiation of comparator atypical antipsychotics (i.e., clozapine, quetiapine, risperidone, olanzapine, aripiprazole, or brexpiprazole).
The evaluation of the study’s primary objective will consist of an observational (noninterventional), population-based cohort of patients with PDP.
This study will be conducted using information collected in US Medicare claims data.

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

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 20/10/2020

Actual: 20/10/2020

Study start date

Planned: 30/09/2021

Actual: 22/10/2021

Date of interim report, if expected

Planned: 31/03/2022

Actual: 24/03/2022

Date of final study report
Planned: 31/03/2024

Actual: 02/06/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Acadia Pharmaceuticals Inc.

Study protocol

0305976 PDP ACADIA mortality protocol 13AUG2021_signed_redacted.pdf
(1001.36 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 topic:

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 compare the risk of mortality among patients with PDP after initiation of pimavanserin with the risk of mortality after initiation of comparator atypical antipsychotics (i.e. clozapine, quetiapine, risperidone, olanzapine, aripiprazole, or brexpiprazole)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

NUPLAZID

Study drug International non-proprietary name (INN) or common name

PIMAVANSERIN

Anatomical Therapeutic Chemical (ATC) code

(N05AX17) pimavanserin

pimavanserin

Medical condition to be studied

Parkinson's disease psychosis

Population studied

Age groups

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

6000

Study design details

Outcomes

All-cause mortality

Data analysis plan

Descriptive statistics will describe the baseline characteristics in the unmatched cohorts.

Exposure propensity scores will be estimated that will be used to control for

confounding by matching the comparator atypical antipsychotic group to the pimavanserin.
Incidence rates and 95% confidence interval (CI) of mortality will be estimated by treatment group, and HRs and 95% CIs in the unmatched and matched cohorts will be estimated with Cox proportional hazards regression models comparing new users of pimavanserin versus new users of atypical antipsychotics.
Estimation of the HRs and 95% CIs will be repeated comparing new users of pimavanserin versus new users of atypical antipsychotics among long-term care residents only.
Secondary analyses evaluating changing hazards over time and in clinically relevant subgroups will be conducted. Sensitivity analyses will be performed.

Documents

Study publications

Layton JB, Forns J, McQuay LJ, Danysh HE, Dempsey C, Anthony MS, Turner ME. Mor…

Layton JB, McQuay L, Forns J, Danysh H, Dempsey C, Anthony M, Turner ME. Risk o…

Rao S, McQuay LJ, Forns J, MacKay R, Danysh HE, Doshi D, Abler V, Anthony MS, L…

Rao S, McQuay LJ, Forns J, MacKay R, Aquilina TC, Doshi D, Abler V, Anthony MS,…

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 source(s), other

US Medicare United States

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug prescriptions

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