Prescription Pattern of Monoamine Oxidase B Inhibitors Combined with Levodopa: A Retrospective Observational Analysis of Italian Healthcare Administrative Databases

First published: 17/07/2024

Last updated: 17/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1000000268

Study ID

1000000268

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Parkinson’s disease is still incurable, and several factors are considered when defining pharmacological therapy. The aim of this study was to describe the prescription pattern of monoamine oxidase B inhibitors (MAO-BIs) marketed in Italy (selegiline, rasagiline, safinamide) as an add-on to levodopa among new users of MAO-BIs, from the perspective of the Italian National Health Service. Through cross-linkage of administrative healthcare data in the Ricerca e Salute (ReS) database, adults with a supply of one or more MAO-BIs in 2017, and with no other MAO-BI use since 2013, were selected. Levodopa had to be supplied within 30 days before/after the MAO-BI. The incidence, use, sex, age, comorbidities, 2-year prescription patterns (i.e., switches, proportion of treated patients per semester/year, mean daily milligrams/monthly tablets supplied, discontinuation, change to other anti-Parkinson drug) of patients taking MAO-BIs were provided. In 2017, 1059 new users received an MAO-BI (incidence 22.6 × 100,000 adults) combined with levodopa: 502 subjects (10.7 × 100,000) were treated with selegiline, 161 (3.4 × 100,000) were treated with rasagiline, and 396 (8.4 × 100,000) were treated with safinamide. The cohorts mainly consisted of males with a median age of ≥ 74 years. Treatment incidences increased with age. Switches occurred in 18.0%, 11.0%, and 4.3% of the selegiline, rasagiline, and safinamide cohorts, respectively. Most of the patients switching from selegiline/safinamide changed to rasagiline, while most of the patients switching from rasagiline changed to safinamide. From the first to second years, patient numbers reduced by ≤ 50%, and the daily milligrams/monthly tablets slightly increased. Six-month discontinuation occurred in > 50% of all cohorts, and ≥ 65% of discontinuing patients changed to another anti-Parkinson drug.

Study status

Finalised

Research institutions and networks

Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

First published: 05/07/2017

Last updated: 01/10/2025

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

Giulia Ronconi ronconi@fondazioneres.it

Study contact

ronconi@fondazioneres.it

Primary lead investigator

Letizia Dondi

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/07/2020

Study start date

Actual: 30/07/2020

Date of final study report
Actual: 16/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Zambon Italy

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:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Retrospective longitudinal cohort study

Main study objective:

To describe the prescription pattern of monoamine oxidase B inhibitors (MAO-BIs) marketed in Italy (selegiline, rasagiline, safinamide) as an add-on to levodopa among new users of MAO-BIs reimbursed by the Italian National Health Service (SSN).

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Medicinal product name

RASAGILINE

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

LEVODOPA

RASAGILINE MESILATE

RASAGILINE TARTRATE

SAFINAMIDE METHANESULFONATE

SELEGILINE

Anatomical Therapeutic Chemical (ATC) code

(N04BA02) levodopa and decarboxylase inhibitor

levodopa and decarboxylase inhibitor

(N04BA03) levodopa, decarboxylase inhibitor and COMT inhibitor

levodopa, decarboxylase inhibitor and COMT inhibitor

(N04BA05) melevodopa and decarboxylase inhibitor

melevodopa and decarboxylase inhibitor

(N04BD01) selegiline

selegiline

(N04BD02) rasagiline

rasagiline

(N04BD03) safinamide

safinamide

Medical condition to be studied

Parkinson's disease

Population studied

Short description of the study population

Starting with the ReS database, we selected adults analyzable from 2013 to 2019 and with at least one supply, in 2017, of one MAO-BI, among selegiline (ATC code: N04BD01), rasagiline (N04BD02) and safinamide (N04BD03).

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

In-hospital and local outpatient settings in public and affiliated with SSN facilities

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Summary results

In 2017, 1059 new users received an MAO-BI (incidence 22.6 × 100,000 adults) combined with levodopa: 502 subjects (10.7 × 100,000) were treated with selegiline, 161 (3.4 × 100,000) were treated with rasagiline, and 396 (8.4 × 100,000) were treated with safinamide. The cohorts mainly consisted of males with a median age of ≥ 74 years. Treatment incidences increased with age. Switches occurred in 18.0%, 11.0%, and 4.3% of the selegiline, rasagiline, and safinamide cohorts, respectively. Most of the patients switching from

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Documents

Study publications

Prescription Pattern of Monoamine Oxidase B Inhibitors Combined with Levodopa: ...

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)

Database of Fondazione ReS

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes