Real world data on new users of atypical antipsychotics: characterization, prescription patterns, healthcare costs and early cardio-metabolic occurrences from a large Italian database

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000261

Study ID

1000000261

DARWIN EU® study

No

Study countries

Italy

Study description

Purpose: To describe new users of atypical antipsychotics (APs) in terms of sociodemographic characteristics, cardiometabolic risk profile, prescription patterns, healthcare costs and cardio-metabolic events over the 24 months after treatment initiation.

Methods: Atypical AP new users were selected from the ReS database and grouped into three: patients already affected by cardiometabolic diseases (group A), patients without these clinical conditions but with predisposing conditions (group B) and patients without cardio-metabolic diseases and predisposing conditions (group C). Annual prescription patterns and healthcare costs were analysed. Subjects of groups B and C were matched with controls to compare the occurrences of cardio-metabolic events over 24 months.

Results: Thirty-two thousand thirty-four new users of atypical APs were selected (median age 69). The 22.3% had cardiometabolic diseases, 14.8% had predisposing conditions and 62.9% had none of these. The 99.3% received monotherapy. The mean annual cost per patient was €2785, and the median cost was €1108. After 24 months, a cardio-metabolic event occurred in 11.5% of group B vs. 8.7% of the controls ($p < .01$), and in 5.0% of group C vs. 2.1% of the controls ($p < .01$).

Conclusion: Patients treated with atypical AP were on average old and, in a non-negligible amount, with cardio-metabolic disease or predisposing conditions. New users of atypical APs showed a significantly higher likelihood to develop a cardio-metabolic event early after treatment initiation.

Study status

Finalised

Research institutions and networks

Institutions

Health Search, Italian College of General Practicioners

Italy

First published: 02/03/2010

Last updated: 20/08/2024

Institution | Educational Institution | Other

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

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Study contact

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Primary lead investigator

Letizia Dondi

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 12/06/2018

Study start date
Actual: 12/09/2018

Date of final study report
Actual: 12/12/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Angelini SpA

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

Retrospective longitudinal case control study

Main study objective:

To describe new users of atypical antipsychotics (APs) in terms of sociodemographic characteristics, cardiometabolic risk profile, prescription patterns, healthcare costs and cardio-metabolic events over the 24 months after treatment initiation.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N05AE) Indole derivatives

Indole derivatives

(N05AH) Diazepines, oxazepines, thiazepines and oxepines

Diazepines, oxazepines, thiazepines and oxepines

(N05AX) Other antipsychotics

Other antipsychotics

Population studied

Short description of the study population

Patients aged ≥ 18 years old and receiving in 2013 (accrual year) one or more prescription of atypical AP were identified by searching the pharmaceutical database.

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 setting in public and affiliated with SSN facilities.

Summary results

Thirty-two thousand thirty-four new users of atypical APs were selected (median age 69). The 22.3% had cardiometabolic diseases, 14.8% had predisposing conditions and 62.9% had none of these. The 99.3% received monotherapy. The mean annual cost per patient was €2785, and the median cost was €1108. After 24 months, a cardio-metabolic event occurred in 11.5% of group B vs. 8.7% of the controls ($p < .01$), and in 5.0% of group C vs. 2.1% of the controls ($p < .01$). Patients treated with atypical AP were on average old and, in a non-negligible amount, with cardio-metabolic disease or predisposing conditions. New users of atypical APs showed a significantly higher likelihood to develop a cardio-metabolic event early after treatment initiation.

Documents

Study publications

Real-world data on new users of atypical antipsychotics: characterisation, pres...

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