

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

**First published:** 15/07/2024

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Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/1000000261>

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### **EU PAS number**

EUPAS1000000261

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### **Study ID**

1000000261

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### **DARWIN EU® study**

No

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## Study countries

Italy

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## 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.

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## 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:** 12/04/2024

**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

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**Study start date**

Actual: 12/09/2018

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**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

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Healthcare resource utilisation

**Data collection methods:**

Secondary use of data

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**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  $\geq 18$  years old and receiving in 2013 (accrual year) one or more prescription of atypical AP were identified by searching the pharmaceutical database.

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## **Age groups**

Adult and elderly population ( $\geq 18$  years)

Adults (18 to  $< 65$  years)

Adults (18 to  $< 46$  years)

Adults (46 to  $< 65$  years)

Elderly ( $\geq 65$  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.

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### **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...

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## Data management

### Data sources

#### Data source(s)

Database of Fondazione ReS

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#### 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

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#### Check completeness

Yes

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**Check stability**

Yes

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**Check logical consistency**

Yes

**Data characterisation**

**Data characterisation conducted**

Yes