

Patients treated with antipsychotics. A follow-up study (Ícaro)

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Study

Ongoing

Administrative details

EU PAS number

EUPAS2807

Study ID

3468

DARWIN EU® study

No

Study countries

Spain

Study description

This study is intended to further explore the metabolic reactions which appear in patients treated with antipsychotic medications, particularly weight gain. The genetic basis of these reactions are a focus of attention, at this regard, a blood

sample is taken from each recruited patient.

Study status

Ongoing

Research institutions and networks

Institutions

Universidad de Valladolid

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[Institution](#)

Contact details

Study institution contact

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Primary lead investigator

Alfonso Carvajal

[Primary lead investigator](#)

Study timelines

Date when funding contract was signed

Planned: 01/01/2009

Actual: 27/04/2009

Study start date

Planned: 01/01/2010

Actual: 18/03/2010

Date of final study report

Planned: 31/12/2013

Sources of funding

- Other

More details on funding

Regional Goverment/ Ministry of Health

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To identify some of the genetic polymorphisms related to weight gain in patients treated with antipsychotics. Other objectives are, to further learn and characterize other adverse reactions, the effectiveness of these medications and the way they are being used in a real setting, finally, an intervention to optimize the use of this medication is foreseen.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N05A) ANTIPSYCHOTICS

ANTIPSYCHOTICS

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

425

Study design details

Outcomes

Weight gain > 7% of initial weight at baseline

Data analysis plan

Risk estimation

Documents

Study, other information

[Autorizacion del Estudio EC11-395 por la AEMPS.pdf \(288.59 KB\)](#)

[DICTAMEN CEIC HCUV EPA-12-78.pdf \(97.71 KB\)](#)

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)

[Other](#)

Data sources (types), other

Prospective patient-based data collection

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