

# Program for safe use of antipsychotics in pediatric population. Online Spanish safety registry for Neuroleptic treatment in children and adolescents (SENTIA)

**First published:** 09/01/2013

**Last updated:** 15/07/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS3264

### Study ID

26719

### DARWIN EU® study

No

### Study countries

Spain

### Study description

The basic methodology of SENTIA is the creation of an extended online database platform which permits a registry of collected data in relation to short-medium-and long-term safety of antipsychotics in children and adolescents. This online application makes multicenter participation possible, and has enormous potential for further study of the safety of antipsychotic drugs in the pediatric population. SENTIA is an online registry (<https://sentia.es>). It is centered in the Child and Adolescent Psychiatry Unit and the Clinical Pharmacology Department of Puerta de Hierro- Hospital and forms part of the “Program for safe treatment with antipsychotics in children and adolescents”. Its objectives are the prevention and early detection of adverse events of these drugs in this population. Children and adolescents, regardless of the diagnosis or clinical symptoms that motivate the prescription, currently under treatment or who are going to initiate treatment with antipsychotics either as monotherapy or combination therapy, are monitored regularly at periods of 1 and 3 months after the initial dose or change of antipsychotic medicine and subsequently, every 6 months for an unlimited period of time. Those who accept to be included in the online Registry are inscribed after completing the Informed Consent. The gathered information is structured as follows: 1-Sociodemographic data, 2- Personal medical and psychiatric history and that of immediate family members (related to very common/serious AE), 3-Clinical assessment: Achenbach Child Behaviour Checklist (CBCL), Mini International Neuropsychiatric Interview (MiniKID), Children’s Global Assessment Scale (CGAS), Clinical Global Impression (CGI), 4- Pharmacological history, 5- Therapeutic compliance (Questionnaire prepared ad hoc), 6- Health habits (Diet, Physical exercise, Toxics), 7- Side effects (AIMS, SAS, SMURF), 8- Physical examination and 9-Biological parameters.

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### **Study status**

Ongoing

## **Research institutions and networks**

## Institutions

Puerta de Hierro-Majadahonda University Hospital

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

Child & Adolescent Psychiatry Unit and the Clinical Pharmacology Service

Basurto Hospital Bilbao. Spain

## Contact details

### **Study institution contact**

Belén Ruiz-Antoran [bruiz.hpth@salud.madrid.org](mailto:bruiz.hpth@salud.madrid.org)

**Study contact**

[bruiz.hpth@salud.madrid.org](mailto:bruiz.hpth@salud.madrid.org)

### **Primary lead investigator**

Belen Ruiz Antoran

**Primary lead investigator**

# Study timelines

## **Date when funding contract was signed**

Actual: 15/01/2010

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## **Study start date**

Actual: 01/01/2011

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## **Data analysis start date**

Actual: 03/12/2012

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## **Date of final study report**

Planned: 31/12/2021

# Sources of funding

- Other

# More details on funding

Ministry of Health, Social Services and Equality, Mutua Madrileña Foundation

# Study protocol

[PROTOCOLO PROYECTO REGISTRO RAM USO ANTIPSICOTICOS PEDIATRIA.pdf](#)  
(117.68 KB)

# 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 type:**

Non-interventional study

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##### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

##### **Main study objective:**

The principal objective of this clinical program is to guarantee a safe use of antipsychotics in children and adolescents through early prevention and detection of adverse events and pharmacological interactions of antipsychotic treatment in pediatric populations. Moreover, close monitoring and long-term follow-up also aims to enhance treatment adherence as well as patient and family alliance.

## Study Design

## **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Prescription event monitoring

## Study drug and medical condition

### **Anatomical Therapeutic Chemical (ATC) code**

(N05A) ANTIPSYCHOTICS

ANTIPSYCHOTICS

## Population studied

### **Age groups**

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

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### **Estimated number of subjects**

250

## Study design details

### **Outcomes**

The potential adverse effects were closely monitored during each office visit using the Safety Monitoring Uniform Report Form. Symptoms related to neurological adverse effects are explored with Sympson-Angus Akatisia Scale

(SAS) and Abnormal Involuntary Movement Scale (AIMS). -Sociodemographic, diagnostic and therapeutic characteristics -Personal medical and psychiatric history-Healthy lifestyle habits-Pharmacological history-Monitoring of therapeutic compliance using a questionnaire prepared ad hoc.-Evaluation of clinical data:CBCL, MiniKID, ASSQ, CGAS and CGI)-Physical examination and electrocardiogram-Biological parameters

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## **Data analysis plan**

Risk estimation

## Documents

### **Study publications**

[Palanca-Maresca I, Ruiz-Antorán B, Centeno-Soto GA, Forti-Buratti MA, Siles A,](#)

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[Palanca-Maresca I, Ruiz-Antorán B, Centeno-Soto G, Jiménez-Fernandez S, García-...](#)

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## 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

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### **Data sources (types), other**

Prescription event monitoring

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No