Longitudinal trends in the use of psychotropic medications in a Spanish pediatric population

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Study Finalised

Administrative details

EU PAS number

EUPAS33028

Study ID

33029

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Background: An increase in prescription of psychotropic medications in children and adolescents has been reported in some countries. We report the evolution in a Health Area in Spain in the period 2013-2017. Aims:To describe psychopharmacologic prescriptions and the users' profile in a paediatric population attending a Mental Health Care Service and its evolution between 2013-2017.Methods: a longitudinal observational study will be carried out. All electronic medical records of the pediatric population (0-18 years old) who attended our mental health area during this period will be included. Each year it will be treated as a specific cohort that includes all patients treated during that year to perform a trend analysis during the 5-year period. Demographic data, psychiatric diagnoses and psychotropic prescription will be collected for all patients treated.

Study status

Finalised

Research institutions and networks

Institutions

Clinical Pharmacology Service, Puerta de Hierro-Majadahonda University Hospital (HUPHM)

Spain

First published: 26/12/2012

Last updated: 20/08/2024

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Belen Ruiz-Antoran

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2016

Actual: 01/05/2016

Study start date

Planned: 01/06/2016

Actual: 01/01/2019

Date of final study report

Planned: 01/01/2020

Actual: 01/01/2020

Sources of funding

- Other

More details on funding

Clinical Pharmacology Service HUPHM

Study protocol

Resumen ESTUDIO DE UTILIZACIÓN DE PSICOFARMACOS EN LA POBLACIÓN PEDIATRICA.pdf(212.04 KB)

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:

Disease epidemiology

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The aim of this study is to describe the usage profile and the evolution of psychotropic medication prescription in specialized mental health care among a local paediatric population in Spain between 2013 and 2017.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Longitudinal observational study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N05) PSYCHOLEPTICS

PSYCHOLEPTICS

(N06A) ANTIDEPRESSANTS

ANTIDEPRESSANTS

(N06) PSYCHOANALEPTICS

PSYCHOANALEPTICS

Population studied

Short description of the study population

Pediatric population (0-18 years old) who attended Mental Health Care Service during the study period.

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

4000

Study design details

Data analysis plan

A descriptive analysis will be carried out using the mean, standard deviation, median and range for continuous variables and counts and percentages for categorical variables. For the subgroup analysis, our population is grouped into one of three categories: babies from 0 to 5 years old, babies from 6 to 11 years old and teenagers from 12 to 18 years old. To determine significantly positive or negative trends over time, the trend tests of the Linear Association by Line will be used for variables with more than two categories analyzed.All statistical analyzes will be performed with the statistical software IBM® SPSS (Statistical Package for the Social Sciences), version 18 (IBM® Corporation, Somers, NY,

USA).

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