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

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Study   Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/33029

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 institution and networks

Institutions

Clinical Pharmacology Service, Puerta de Hierro-Majadahonda University Hospital (HUPHM)
Spain
First published: 26/12/2012
Last updated 17/05/2019

Institution

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

Contact details

Study institution 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
100000097448
PSYCHOLEPTICS
100000097650
ANTIDEPRESSANTS
100000097649
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

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