USE OF PSYCHOTROPIC DRUGS IN CHILDREN AND ADOLESCENTS IN CATALONIA. A cohort study with real world data from the electronic primary health care record from 2007-2017. (PEPSICAT)

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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/28503

EU PAS number
EUPAS28375

Study ID
28503

DARWIN EU® study
No

Study countries
Spain

Study description
This project has four main objectives: to describe in children <18 years the use of psychotropic drugs during the last decade, to describe their psychiatric diagnoses, to describe the baseline characteristics when starting treatment with psychotropic drugs and, to describe the consumption pattern of psychotropic drugs. As secondary objectives: to analyse factors associated with the use of different psychotropic drugs and factors related

to the diagnosis of mental illness in patients under treatment with psychotropic drugs and to describe the adherence to psychotropic treatment. As exploratory objectives, an attempt will be made to correlate the maternal obstetric and psychiatric history with the consumption of psychotropic medication in the offspring and to analyse the reasons for the lack of a diagnostic record of mental pathology in patients with psychotropic treatment. Methods: Descriptive observational study will from 2007-2017 in the population under the age of 18 with at least one prescription for a psychotropic drug. Two studies will be carried out: one to estimate the prevalence of psychotropic drug use and psychiatric pathology diagnoses and the second one to estimate the incidence of psychotropic drug use in the <18 year population. This population will be followed until the end of the study or the impossibility to obtain information (death/transfer). The treatment period with this first psychotropic drug and the addition of other psychotropic drugs or the change of psychotropic treatment will be analysed during the follow-up. Data source: SIDIAP (Sistema de Información para el Desarrollo de la Investigación en Atención Primaria) database, which contains anonymized clinical information on approximately 80% of the population of Catalonia (Spain). Information will be completed with data from the Basic Minimum Data Set for outpatient mental health care (CMBD-SMA). Data will be stratified by sex and age groups.

Study status
Ongoing

Research institution and networks

Institutions

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain
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23/02/2024

Institution
Educational Institution
Laboratory/Research/Testing facility
Not-for-profit
ENCePP partner

Contact details

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Study timelines

Date when funding contract was signed
Planned:
16/02/2018

Study start date
Planned:
01/06/2018
Actual:
01/06/2018

Data analysis start date
Planned:
14/06/2018

Date of interim report, if expected
Planned:
05/10/2018
Actual:
05/10/2018

Date of final study report
Planned:
31/12/2020

Sources of funding

- Other

More details on funding

Catalan Health Department

Study protocol

PEPSICAT_ENCePP.pdf(283.36 KB)

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Other study registration identification numbers and links

Catalan Health Department SLT006/17/00309https://web.gencat.cat/web/shared/OVT/Departaments/SLT/Documents/Formularis_definitiva-de-concessio-de-la-subencio-PERIS-2018-2020.pdfAEMPS classification: EPA-OD. UMO 2007-17. Code: IUI-FLU-2018-01

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Drug utilisation

Main study objective:
To describe the use of psychotropic drugs in children <18 years from Catalonia during 2007-2017.To describe the psychiatric diagnoses in the <18 years population consuming psychotropic drugs.To describe the consumption pattern and characteristics of patients <18 years who start treatment with psychotropic drugs.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(N06BA) Centrally acting sympathomimetics
(N06A) ANTIDEPRESSANTS
(N05A) ANTIPSYCHOTICS
(N05B) ANXIOLYTICS
(N05C) HYPNOTICS AND SEDATIVES

Medical condition to be studied
Psychiatric investigation

Population studied

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
300000

Study design details

Data analysis plan
All data management, purification, descriptive calculation and statistical analysis processes will be carried out using the statistical package R 3.3(2016)Demographic data and baseline characteristics of the population will be described by relative and absolute frequencies for the categorical variables and median standard deviation or median and interquartile range for the continuous variables.In the bivariate analysis, Chi-square test or the exact Fischer test for the categorical variables and the t-test of Student or the U-test of Mann-Whitney for the continuous variables according to their distributionEvaluation of psychotropic consumption based on psychiatric/obstetric maternal records, as well as the risk related to the persistence/adherence of these in patients with an age range of 16 to 18 years old, will be performed using multiple logistic regression models or proportional risk models (Cox).Adjustment for risk factors based on the characteristics of the study population

Data management

Data sources

Data source(s)
The Information System for Research in Primary Care (SIDIAP)

Data source(s), other
SIDIAP

Data sources (types)
Administrative data (e.g. claims)
Drug dispensing/prescription data
Electronic healthcare records (EHR)

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