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

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/26719

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.

Study status

Ongoing

Research institutions and networks

Institutions

Puerta de Hierro-Majadahonda University Hospital

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Institution

Child & Adolescent Psychiatry Unit and the Clinical Pharmacology Service

Basurto Hospital Bilbao. Spain

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
Actual: 15/01/2010

Study start date
Actual: 01/01/2011

Data analysis start date
Actual: 03/12/2012

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

Is the study required by a Risk Management Plan (RMP)?

Not applicable

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:

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

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)

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

Data analysis plan

Risk estimation

Documents

Study publications

Palanca-Maresca I, Ruiz-Antorán B, Centeno-Soto GA, Forti-Buratti MA, Siles A, ...

Palanca-Maresca I, Ruiz-Antorán B, Centeno-Soto G, Jiménez-Fernandez S, García-...

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prescription event monitoring

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