Off-label use of neuroleptics and antidepressants and risks of psychostimulant use in ADHD patients during childhood and adolescents (OLUNAR)

First published: 08/07/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/17515

EU PAS number

EUPAS7034

Study ID

17515

DARWIN EU® study

No

Study countries

Germany

Study description

Based on data from statutory health insurance (SHI) providers, the study focuses on the off-label use of antipsychotic and antidepressant drugs in children and adolescents and evaluates the related risks and side effects (first part). Furthermore, the risks of stimulant use in children and adolescents with attention deficit and hyperactivity disorder (ADHD) are investigated (second part).

Study status

Finalised

Research institutions and networks

Institutions

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 26/02/2024

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Oliver Riedel

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/10/2012

Actual: 29/10/2012

Study start date

Planned: 16/07/2013

Actual: 16/07/2013

Data analysis start date

Planned: 18/12/2013

Actual: 18/12/2013

Date of interim report, if expected

Planned: 12/06/2014

Actual: 12/06/2014

Date of final study report

Planned: 31/12/2015

Actual: 31/10/2015

Sources of funding

- Other

More details on funding

Federal Institute for Drugs and Medical Devices

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The objectives are to examine the extent of off-label use of antidepressant(ATDs) and antipsychotic(AP) drugs in children and adolescents and to estimate the risk of specific adverse events associated with off-label use of these drugs. Also, we evaluate the cardio- and cerebrovascular risks of methylphenidate use compared to nonuse for the treatment of children and adolescents with ADHD in Germany

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N05A) ANTIPSYCHOTICS

ANTIPSYCHOTICS

(N06A) ANTIDEPRESSANTS

ANTIDEPRESSANTS

(N06BA04) methylphenidate

methylphenidate

Medical condition to be studied

Completed suicide

Cardiovascular disorder

Cerebrovascular disorder

Neuroleptic malignant syndrome

Extrapyramidal disorder

Ischaemic stroke

Myocardial infarction

Angina pectoris

Cardiomyopathy

Death

Population studied

Short description of the study population

Children and adolescents with attention deficit and hyperactivity disorder (ADHD) who use antidepressant (ATDs) and antipsychotic(AP) drugs.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Special population of interest

Other

Special population of interest, other

Attention deficit and hyperactivity disorder (ADHD) patients

Estimated number of subjects

2000000

Study design details

Outcomes

Risks and side effects, including Drug-induced obesity, Hyperglycemia, Diabetes mellitus, Hyperprolactinemia, Malignant neuroleptic syndrome, Drug-induced parkinsonism, Drug-induced dystonia / tardive Dyskinesia, Drug-induced tremor, Poisoning by psychotropic drugs, Myocardial infarction, Stroke, Bradycardia / Tachycardia, Cardiomyopathy, Heart failure, Suicide risk, All-cause mortality, in the second part of the study (methylphenidate in children with ADHD): cardiac arrhythmia, angina pectoris, cardiomyopathy and all-cause mortality

Data analysis plan

In both study parts, prevalence and incidence rates of the considered medications will be determined.First part: for the antipsychotic cohort, the primary analysis will be a Cox regression analysis estimating the adjusted hazard ratio (HR) for metabolic and endocrine adverse effects in off-label users vs. on-label users. For the antidepressant cohort, the primary analysis will be a

Cox regression analysis estimating the adjusted HR for cardio- and cerebrovascular side effects in off-label users vs. on-label users.Second part: a time-dependent Cox proportional hazard model will be used to estimate the adjusted hazard ratio for major cardio-cerebrovascular events in current MPH use vs. nonuse.

Documents

Study publications

Schröder C, Dörks M, Kollhorst B, Blenk T, Dittmann RW, Garbe E, Riedel O. Outp…

Schröder, C., Dörks, M., Kollhorst, B. et al. Outpatient antipsychotic drug use…

Data management

Data sources

Data source(s)

German Pharmacoepidemiological Research Database

Data sources (types)

Administrative healthcare records (e.g., claims)

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

Unknown