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

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# Administrative details

**Study description** 

EU PAS number	
EUPAS7034	
Charles ID	
Study ID	
17515	
DARWIN EU® study	
No	
Study countries	
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Germany	

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



# Contact details

### **Study institution contact**

Oliver Scholle scholle@bips.uni-bremen.de

Study contact

### **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

# 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

### 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

### **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 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

# Unknown

### **Check completeness**

**Check conformance** 

Unknown

### **Check stability**

Unknown

# **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

Unknown