Attention Deficit Hyperactivity Disorder Drugs Use Chronic Effects: Results from the National Health Survey for Children and Adolescents (KiGGS) (ADDUCE)

First published: 06/05/2014

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS4551

Study ID

6902

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The primary aim of this study is to examine the potential association between the use of methylphenidate and adverse outcomes using data from the German Health Interview and Examination Survey for Children and Adolescents formally conducted by the Robert Koch Institute. The KiGGS dataset is a nationwide, representative cross-sectional health interview and examination survey with a total of 17641 examined children and adolescents aged 0-17 years. The survey was conducted between May 2003 and 2006 in 167 sample points all over Germany. Participants of the survey were medically and physically examined and tested. Three groups will be identified, i) children and adolescents who have an ADHD code and a methylphenidate code (treatment group), ii) children and adolescents who have an ADHD code but do not have a methylphenidate code (ADHD controls), children and adolescents who do not have an ADHD code or methylphenidate code (Non-ADHD controls). The adverse outcomes to be studied include cardiovascular outcomes e.g. blood pressure, pulse, recorded cardiovascular diagnoses, growth outcomes e.g. height and weight, seizures. Propensity scoring methodology will be used in the analysis of these data.

Study status

Ongoing

Research institutions and networks

Institutions

University of Dundee

United Kingdom

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Institution | Educational Institution

Division of Neuroscience,Medical Research Institute

Networks

EUropean NETwork for HYperkinetic DISorders (EUNETHYDIS)

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Network

Contact details

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Study contact

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Primary lead investigator

David Coghill

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/10/2010

Actual: 29/10/2010

Study start date
Planned: 01/01/2011

Actual: 01/12/2011

Data analysis start date
Planned: 01/08/2012

Actual: 01/10/2012

Date of final study report
Planned: 01/10/2014

Sources of funding

- Other

More details on funding

FP7-HEALTH Grant 260576, University Hospital Erlangen

Regulatory

Was the study required by a regulatory body?

Yes

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To examine the potential association between the use of methylphenidate and adverse outcomes using data from the KIGGs dataset.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

METHYLPHENIDATE HYDROCHLORIDE

Medical condition to be studied

Attention deficit hyperactivity disorder

Cardiovascular disorder

Partial seizures

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

12373

Study design details

Outcomes

Blood pressure: systolic and diastolic blood pressure, Pulse, growth, seizures

Data analysis plan

The multiple propensity score method will be used, multiple PS is estimated using multinomial logistic regression analysis. To estimate the treatment effects while controlling for initial differences, the multiple PS, which are calculated for each treatment category, are included as extra predictors in the regression analysis.

Data management

Data sources

Data source(s), other

The German Health Interview and Examination Survey for Children and Adolescents Germany

Data sources (types)

Other

Data sources (types), other

KiGGS study is a nationwide, representative, cross-sectional health interview and examination survey.

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