Attention Deficit Hyperactivity Disorder Drugs Use Chronic Effects observational, open label pharmacovigilance study (ADDUCE)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/3986

EU PAS number

EUPAS3985

Study ID

3986

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] Hungary
- [ ] Italy
- [ ] United Kingdom

Study description

This is a 2 year naturalistic pharmacovigilance European multicentre study investigating the long-term safety of methylphenidate in children and young people aged between 6 and 17 years. Clinicians of participating centres in Hungary, Italy, Germany and the United Kingdom will compare 800 patients with attention deficit hyperactivity disorder (ADHD) who are newly prescribed methylphenidate in a 2 year longitudinal naturalistic prospective design with two control groups, 400 children without ADHD matched for age, gender and socio-economic status and 400 patients with ADHD not prescribed ADHD medications. The primary focus will be on adverse effects affecting growth and development, the neurological and cardiovascular systems, and psychiatric symptoms. Participants of all three groups (i.e., medicated ADHD, unmedicated ADHD, non-ADHD) will all have identical assessments throughout the study. Full assessments will take place at baseline and thereafter at 6, 12 and 24-months to assess effectiveness of treatment and potential adverse events. Comparisons will be made with ADHD subjects not being treated with medication and children without ADHD matched for age, gender and socio-economic status.

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

University of Dundee Dundee, UK, NHS Fife UK, NHS Lothian UK, Northumberland, Tyne and Wear NHS Trust UK, Tees, Esk and Wear Valley NHS Trust UK, Zentralinstitut fuer Seelische Gesundheit Mannheim, Germany, Klinik und Poliklinik für Kinder- und Jugendpsychiatrie, Psychosomatik und Psychotherapie Würzburg, Germany, Klinik für Psychiatrie, Neurologie, Psychosomatik und Psychotherapie im Kindes- und Jungendalter

Rostock, Germany, Università degli Studi di Cagliari Cagliari, Italy, 16 more study centres in UK, Germany, Italy, Hungary

Networks

EUropean NETwork for HYperkinetic DISorders (EUNETHYDIS)

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Network

Contact details

Study institution contact

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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: 29/10/2010

Actual: 01/02/2011

Study start date
Planned: 16/01/2012

Actual: 30/01/2012

Data analysis start date
Planned: 01/01/2015

Date of final study report
Planned: 31/10/2015

Sources of funding

- EU institutional research programme
- Other

More details on funding

FP7-HEALTH Grant 260576, Participating Centres

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 establish three prospective cohorts of children and adolescents and to conduct a 24-month prospective open-label naturalistic observational cohort pharmacovigilance study to provide data required to answer several specific scientific questions about prevalence, clinical significance, and development for four specific classes of potential long-term adverse effects of methylphenidate use.

Study Design

Non-interventional study design

Cohort

Case-control

Other

Non-interventional study design, other

Observational open-label pharmacovigilance study

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

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

1600

Study design details

Outcomes

The primary outcome is the height velocity standard deviation scores (SDS) which is defined as: (Child’s height velocity - mean height velocity for sex & age) / (Standard Deviation of height velocity for sex & age). Secondary outcome parameters refer to growth, cardiovascular system, psychiatric and neurological measurements.

Data analysis plan

Characteristics of subjects included in the study will be described using the “5 number statistics” for quanitative variables and percentages for categorical variables. Traditional trivariate/bivariate comparisons will be done to compare the groups (ANOVA, chi-square tests and non-parametric tests, according to their conditions of validity).Incidence rates of side effects will be estimated in each of the 3 groups, but not compared statistically. The association with all primary and secondary endpoints will be statistically tested with all potential covariates of interest using traditional procedures (correlations, ANOVA, chi-

square tests or non-parametric tests, according to their conditions of validity).The child’s height velocity will be estimated from all available data using simple linear regression of height with time.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Case-control surveillance database

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