The relationship between the month of birth and ADHD treatment

First published: 28/04/2017

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/41916

EU PAS number

EUPAS18732

Study ID

41916

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

****This study has been cancelled before data collection due to lack of time by the researchers**** There seems to be a relationship between a child's month of birth and the diagnosis and treatment of attention deficit hyperactivity disorder (ADHD). Both underdiagnosis as well as overdiagnosis of ADHD can have consequences for the future of a child. The objective of this study is to determine if there is a relationship between the month of birth and the pharmacological treatment of ADHD in children in the Netherlands. The study cohort includes children and adolescents ≤ 24 years old who use ADHD medication, dispensed for the first time between 2006-2016.

Study status

Finalised

Research institutions and networks

Institutions

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

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Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Rob Heerdink

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2017

Actual: 01/02/2017

Study start date

Planned: 01/06/2017

Actual: 01/06/2017

Date of final study report

Planned: 01/01/2018

Actual: 07/07/2021

Sources of funding

- Other

More details on funding

Division of Pharmacoepidemiology & Clinical Pharmacology

Study protocol

20170426 ADHD_birthmonth_def3.pdf(561.42 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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Is there a relationship between the month of birth and the pharmacological treatment of ADHD in children and adolescents?

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Descriptive

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06BA04) methylphenidate

methylphenidate

(N06BA02) dexamfetamine

dexamfetamine

(N06BA09) atomoxetine

atomoxetine

Medical condition to be studied

Attention deficit hyperactivity disorder

Population studied

Short description of the study population

The study cohort will include children and adolescents (hereafter referred to as children) ≤ 24 years old who use attention deficit hyperactivity disorder (ADHD) medication for the first time (incident users).

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Estimated number of subjects

20000

Study design details

Outcomes

The start of ADHD medication.

Data analysis plan

The analysis will be descriptive. The children receiving ADHD medication with a different month of birth will be compared. The age at which a child receives the treatment for the first time will be defined, it will be represented as the number of months from birth until the first dispensing date. Also the period the children use the ADHD medication will be analysed. The measures of occurrence and association are the incidence rates and the relative risks.Analyses are stratified according to sex, age categories and the calendar year the ADHD medication is dispensed for the first time. We will correct for the total number of births in different months/years.

Data management

ENCePP Seal

Conflicts of interest of investigators

Conflicts of interest.pdf(82.12 KB)

Data sources

Data source(s)

PHARMO Data Network

Data sources (types)

Drug dispensing/prescription data

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