DARWIN EU® – Trends in utilisation of Attention-Deficit Hyperactivity Disorder (ADHD) Medications

First published: 19/06/2024
Last updated: 12/07/2024

Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/1000000219

EU PAS number
EUPAS1000000219

Study ID
1000000219

DARWIN EU® study
Yes

Study countries
Belgium
Germany
Netherlands
Spain
United Kingdom

Study description
The overall aim of this study is to characterise the use of ADHD medications in the period of 2010 to 2023. The specific objectives are:
1. To estimate the monthly and yearly period prevalence of use of each ADHD medicine, overall and stratified by age and gender in each database.
2. To estimate the monthly, quarterly, and yearly incidence of use of each ADHD medicine, overall and stratified by age and gender in each database.

3. Among new users of each ADHD medicine, to identify the indication at the time of the initial prescribing/dispensing, overall and stratified by age, sex, and quarter.
4. Among new users of each ADHD medicine, to estimate the initial dose, cumulative dose, and time on treatment of the initial medication, overall and stratified by age, sex, indication at index, and quarter.
5. Among new users of any ADHD medicine, to estimate the total treatment duration, number of prescriptions overall and by medicine., stratified by initial medicine and quarter of the year.
6. To identify the treatment pathway of each individual who initiated an ADHD medicine, including treatment add-on, switch and concurrent medication/co-prescribing, stratify by calendar time of initiation.

Study status
Planned

Research institution and networks

Institutions

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

United Kingdom
First published: 01/02/2024
Last updated
01/02/2024

Institution
Educational Institution
Hospital/Clinic/Other health care facility

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

Belgium
Croatia
Denmark
Estonia
Finland

France
Germany
Hungary
Netherlands
Norway
Portugal
Spain
United Kingdom
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Network

Contact details

Study institution contact
Ilse Schuemie
Study contact

study@darwin-eu.org
Primary lead investigator
Xintong Li
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
26/03/2024
Actual:
26/03/2024

Study start date
Planned:
26/06/2024

Data analysis start date
Planned:
12/08/2024

Date of final study report
Planned:

30/09/2024

Sources of funding

- EMA

Study protocol

DARWIN EU_D2.2.3_Protocol_P3-C1-004_DUS_ADHD_V4.pdf(2.01 MB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study type list

Study topic:
Disease /health condition

Study type:
Non-interventional study

Scope of the study:
Drug utilisation

Data collection methods:
Secondary data collection

Study design:
Cohort studies will be conducted using routinely collected health data from 6 databases. The study will comprise two consecutive parts (see protocol).

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine, other
Lisdexamfetamine (N06BA12)
Methylphenidate (N06BA04)
Atomoxetine (ATC code: N06BA09)
Dexamfetamine (N06BA02)
Guanfacine (C02AC02)

Study drug International non-proprietary name (INN) or common name
ATOMOXETINE
GUANFACINE HYDROCHLORIDE
METHYLPHENIDATE

Anatomical Therapeutic Chemical (ATC) code
(C02AC02) guanfacine
(N06BA02) dexamfetamine
(N06BA04) methylphenidate
(N06BA09) atomoxetine
(N06BA12) lisdexamfetamine

Medical condition to be studied
Attention deficit hyperactivity disorder

Additional medical condition(s)
ADHD

Population studied

Short description of the study population
Population-level utilisation of ADHD medications: general population.
All people aged 3 years and older (Rocco et al. 2021), registered in the respective databases since the 1st of January of 2010 to the latest available data, with at least 365 days of prior data availability, will participate in the population-level analysis of period prevalence and incidence of ADHD medications of interest.
Patient-level utilisation of ADHD medications: new user cohort.
In objective 3 and 4, new user cohort of each ADHD medication will be created at drug substance level, using 365 days washout window.
In objective 5 and 6, new users will be identified using the first record of any of the ADHD medications of interest within the study period, having no previous records for ANY study medication any time prior to entry. The index date will be defined as the date of the first eligible medication record.
Five new user cohorts of the medications licensed for ADHD treatment will be constructed separately: the stimulants dexamphetamine, lisdexamfetamine, and methylphenidate, and the non-stimulants atomoxetine and guanfacine.

Age groups
Paediatric Population (< 18 years)
Children (2 to < 12 years)
Adolescents (12 to < 18 years)
Adult and elderly population (>18 years)
Adults (18 to < 65 years)
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Elderly (? 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Study design details

Setting
This study will be conducted using routinely collected data from 6 databases in 5 European countries. All databases were previously mapped to the OMOP CDM.

Data management

Data sources

Data source(s)
Clinical Practice Research Datalink (CPRD) GOLD

IPCI
The Information System for Research in Primary Care (SIDIAP)
Longitudinal Patient Data - Belgium
Disease Analyzer Germany
Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

Use of a Common Data Model (CDM)

CDM mapping
Yes

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
Unknown