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

First published: 19/06/2024

Last updated: 14/03/2025

Study Finalised

Administrative details

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

Finalised

Research institutions 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
☐ Greece
☐ Hungary
☐ Italy
☐ Netherlands
☐ Norway

☐ Portugal

☐ Spain

☐ Sweden

☐ United Kingdom

First published: 01/02/2024

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Network

Contact details

Study institution contact

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Study contact

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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

Actual: 24/02/2025

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 use of data

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

guanfacine

(N06BA02) dexamfetamine

dexamfetamine

(N06BA04) methylphenidate

methylphenidate

(N06BA09) atomoxetine

atomoxetine

(N06BA12) lisdexamfetamine

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.

Documents

Study report

DARWIN EU_Report_P3-C1-004_ADHD_V5.pdf(3.02 MB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink (CPRD) GOLD

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

IQVIA Longitudinal Patient Data - Belgium

IQVIA Disease Analyzer Germany

BIFAP - 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

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown