Post-authorisation Safety Study to Evaluate the Long-term Safety of Dexamfetamine (Amfexa) (PASS for dexamfetamine)

First published: 27/10/2014

Last updated: 04/10/2021

Study Finalised

Administrative details

EU PAS number

EUPAS7782

Study ID

43105

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ United Kingdom
- ☐ United States

Study description

A PASS to further analyse the safety of dexamfetamine specifically targeting assessment of: • cardiovascular events • growth relating to sexual maturation • psychiatric disorders • sexual maturity disorders

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dieter Fritsch

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 29/07/2016

Actual: 22/06/2016

Study start date
Planned: 01/09/2016

Actual: 01/01/2015

Data analysis start date
Planned: 01/01/2017

Actual: 01/01/2017

Date of interim report, if expected
Planned: 01/01/2017

Actual: 27/01/2017

Date of final study report
Planned: 31/12/2020

Actual: 17/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Medice

Study protocol

Medice dexamfetamine PASS protocol v6 0 01-06-2016.pdf(920.82 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Assess the incidence proportion and incidence rate for cardiovascular, psychiatric and growth related adverse events Compare the relative risk of long-term cardiovascular, psychiatric and growth related adverse events

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Post-authorisation Safety Study (PASS)

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N06BA02) dexamfetamine

dexamfetamine

Medical condition to be studied

Cardiovascular disorder

Psychiatric symptom

Delayed puberty

Growth retardation

Population studied

Short description of the study population

ADHD children newly exposed to dexamfetamine or another stimulant

Inclusion criteria

- Boys and girls 6 to 17 years of age at the time of first stimulant prescription
- At least 1 diagnosis of ADHD based on

o Read code (THIN) (e.g., E2E0.00 child attention deficit disorder, E2E0100 attention deficit with hyperactivity, etc.)

o Three character ICD10 code, i.e., F90 (German DA)

o ICD 9 codes, i.e., 314.01 (PharMetrics Plus)

- At least 1 prescription of a stimulant (dexamfetamine, methylphenidate or lisdexamfetamine) used for the treatment of ADHD (refer to Annex 3 for list of drug codes)
- At least 6 months of enrolment in the database prior to first prescription of stimulant

Exclusion criteria

The following exclusion criteria apply to all three databases:

- Previous diagnosis of cardiovascular disease, psychiatric illness, or impairment in growth or sexual maturation, to be applied for each subcohort separately (see table in Section 9.3.1). For example, for cohort 1 that has incident cardiovascular events as outcome of interest, only patients with a history of cardiovascular disease will be excluded.

- History of narcolepsy (all four cohorts)
- Congenital heart disorders (all four cohorts)

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Special population of interest

Other

Special population of interest, other

Patients with Cardiovascular disorder, Psychiatric symptom, Delayed puberty, Growth retardation

Estimated number of subjects

5000

Study design details

Data analysis plan

Descriptive analyses will be performed to compare populations who have taken dexamfetamine with those who have taken other stimulants on the market. Incidence proportions and incident rates of each AE grouping will be provided. Multivariate analysis will be performed for each adverse event of interest using regression methods as appropriate to control for any potential confounders. Stratification based on sex and dosage will also be conducted.

Documents

Study results

Dexamfetamine PASS Abstract of Final Report V3 18-05-2021 privacy.pdf(76.66 KB)

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

IQVIA Disease Analyzer Germany

Data source(s), other

IMS LifeLink: PharMetrics Plus - US

Data sources (types)

Electronic healthcare records (EHR)

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