Drug Utilisation Study of Intuniv® (guanfacine extended release) in European Countries, Study protocol I: Database study (Intuniv data base study Europe)

First published: 25/04/2017

Last updated: 11/11/2024

Study Finalised

Administrative details

EU PAS number

EUPAS18735

Study ID

48508

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Germany
- ☐ Norway

- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

This is a multi-country drug utilization study using retrospective database analysis. A single database for all target countries is not available. Therefore an approach was chosen which includes multiple data sources to gather drug utilization data for Intuniv in European target countries. In case longitudinal patient level data do not exist in a target country, a prescriber survey will be conducted, which is described in a separate protocol.

Study status

Finalised

Research institutions and networks

Institutions

Real World Solutions, IQVIA

- [ ] Netherlands
- [ ] United Kingdom (Northern Ireland)

First published: 28/04/2011

Last updated: 22/03/2024

Institution | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dorothea von Bredow

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/08/2016

Actual: 30/08/2016

Study start date

Planned: 01/02/2019

Actual: 15/11/2018

Date of interim report, if expected

Planned: 30/06/2019

Actual: 11/06/2019

Date of final study report

Planned: 30/06/2023

Actual: 01/05/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda Pharmaceutical Company Limited

Study protocol

INTUNIV EU DUS_DATABASE Protocol v7.0_17Jul2018clean-redact.pdf (16.67 MB)

INTUNIV_EU_DUS_Protocol Amend v7.2_CLEAN_FINAL_26-JUL-2022_redacted.pdf (564.71 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Overall: Drug utilization study for the next 5 years with Intuniv® with annual data in European countries. Study objectives: 1.characterize patients, focussing on indications other than ADHD, children <6 years, adults 2. describe prescribing patterns of Intuniv® among physicians 3. assess compliance with indication, visits and measurements needed during the first year of treatment</6></6>

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multi-country retrospective analysis

Study drug and medical condition

Medicinal product name

INTUNIV

Study drug International non-proprietary name (INN) or common name

GUANFACINE HYDROCHLORIDE

Anatomical Therapeutic Chemical (ATC) code

(A) ALIMENTARY TRACT AND METABOLISM

ALIMENTARY TRACT AND METABOLISM

(C02AC02) guanfacine

guanfacine

Medical condition to be studied

Attention deficit hyperactivity disorder

Population studied

Short description of the study population

The study population included patients with attention deficit hyperactivity disorder (ADHD) who have been prescribed Intuniv® identified from the electronic medical record databases and national registries.

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with attention deficit/hyperactivity disorder

Estimated number of subjects

5000

Study design details

Data analysis plan

The analysis will be done descriptively as specified in the statistical analysis plan.

Documents

Study results

Intuniv EU database study redacted abstract final report.pdf (2.94 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

THIN® (The Health Improvement Network®)

Longitudinal Patient Data Spain - OMOP

The Norwegian Prescribed Drug Registry

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

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