Drug utilisation study of Intuniv® (guanfacine extended release) in European Countries – A prescriber survey (Intuniv survey study Europe)

First published: 26/04/2017

Last updated: 11/11/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48514

EU PAS number

EUPAS18739

Study ID

48514

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Finland
- [ ] Ireland
- [ ] Netherlands

Study description

This is a multinational, cross-sectional, non-interventional and anonymous survey to assess drug utilisation of Intuniv which is indicated for treatment of attention deficit hyperactivity disorder. The survey will be carried out among physicians who will be asked to provide de-identified patient data. The survey will be conducted through a web-questionnaire among prescribers of Intuniv® in four European countries (Belgium, Finland, Ireland, Netherlands). In other countries utilization of Intuniv will be assessed in a database analysis 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

Matthew Page

Study contact

matt.page@takeda.com

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: 20/02/2019

Date of interim report, if expected

Planned: 30/06/2019

Actual: 11/06/2019

Date of final study report

Planned: 30/06/2022

Actual: 16/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda Pharmaceutical Company Limited

Study protocol

INTUNIV EU DUS_SURVEY Protocol v5.0_17Jul2018_redacted.pdf(305.77 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:

Primary data collection

Main study objective:

Overall: Drug utilization study with Intuniv® in European countries until 2021. Results will be reported annually. 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

Cross-sectional

Other

Non-interventional study design, other

Multinational, non-interventional and anonymous survey

Study drug and medical condition

Name of medicine

INTUNIV

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

GUANFACINE HYDROCHLORIDE

Anatomical Therapeutic Chemical (ATC) code

(C02AC02) guanfacine

guanfacine

Medical condition to be studied

Attention deficit hyperactivity disorder

Population studied

Short description of the study population

A survey of physicians prescribing Intuniv® for the treatment of attention deficit/hyperactivity disorder (ADHD) in Belgium, Finland, Ireland, and Netherlands from 2019 to 2022.

Inclusion criteria:

• Prescribers of Intuniv®, i.e. physicians who know and have prescribed the drug at least once during the previous 12 months (or, for the first report, since country specific launch) (paediatricians, psychiatrists, neurologists and GPs).

Exclusion criteria:

Inactive and retired physicians (when documented information is available to identify them) will be deleted from the contact lists before randomisation.

The following exclusion criteria will be checked at the beginning of the web questionnaire:

• Physicians who do not treat patients or who may have a conflict of interest (i.e. physicians employed by regulatory bodies or pharmaceutical industries).

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

1000

Study design details

Data analysis plan

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

Documents

Study results

Intuniv EU survey study redacted abstract final report.pdf(3.69 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Data will be collected within a survey conducted among a representative sample of physicians known to treat patients with ADHD. The survey will collect data from the following sources: • physicians files (OneKey lists) • information collected by a web questionnaire, including de-identified patient 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