SHP503-803: Drug Utilization Study with Intuniv® in Australia

First published: 28/04/2021

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS40684

Study ID

44620

DARWIN EU® study

No

Study countries

Australia

Study description

This study will evaluate and analyze prescribing behaviors of physicians and determine whether Intuniv was correctly prescribed in Australia.

Study status

Finalised

Research institutions and networks

Institutions

Shire

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Study Contact Shire ClinicalTransparency@shire.com

Study contact

ClinicalTransparency@shire.com

Primary lead investigator

Study Contact Shire

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/05/2017

Study start date
Actual: 11/03/2019

Data analysis start date
Actual: 01/05/2019

Date of interim report, if expected
Actual: 28/08/2020

Date of final study report
Actual: 27/08/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Shire

Study protocol

SHP503-803- protocol-original-redact.pdf (758.68 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

CT.gov: NCT04866030,To obtain more information on the study, click here/on this link: https://clinicaltrials.takeda.com/study-detail/609017abf89629001e47b500

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:

Combined primary data collection and secondary use of data

Main study objective:

The overall objective is to provide data on an annual basis for 3 years in Australia to evaluate drug utilization and monitor off-label use of Intuniv®

Study drug and medical condition

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

Intuniv® for treatment of ADHD in children and adolescents in Australia in 2018

Patients who have been prescribed Intuniv at least once during the reporting period. For this third (final) study report, the observation period was from 01 February 2020 to 31 January 2021 for the annual and from 01 February 2018 (the launch date in Australia) to 31 January 2021 for the cumulative reporting period.

Subjects and Study Size, Including Dropouts

The following numbers of patients and prescriptions are included in this third (final) report.

• NostraData database:

o Annual reporting period: 21,028 patients, 152,837 prescriptions

o Cumulative reporting period: 27,461 patients, 260,460 prescriptions

• Annual physician survey (2021): 26 physicians, 104 patients.

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)

Special population of interest

Other

Special population of interest, other

Patients with attention deficit hyperactivity disorder

Estimated number of subjects

100

Study design details

Outcomes

1.Number of Participants Based on Indication of Use of Intuniv 2.Number of Participants with Presence/Absence of Contraindications, 1.Number of Participants Based on Patterns of Drug Use 2.Number of Participants Stratified by Prescriber Information Based on Physician Survey 3.Frequency of Weight Monitoring of Participants by Physician 4.Frequency of Blood Pressure Monitoring of Participants by Physician 5.Frequency of Heart Rate Monitoring of Participants by Physician

Data analysis plan

Descriptive analyses will be performed based on the prescriptions contained in the NostraData database from each 12-month reporting period. The use of Intuniv® will be analysed using the prescriptions collected during the 3-year assessment period.

Documents

Study results

SHP503-803-clinical-study-report-redact.pdf (732.02 KB)

Data management

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 sources (types)

Drug dispensing/prescription data

Other

Data sources (types), other

Prescription event monitoring

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