SHP617-404: A SWEDISH RETROSPECTIVE STUDY EVALUATING THE PATTERN OF PLENADREN USE FROM SWEDISH QUALITY REGISTRIES (SWE-DUS)

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Study Finalised

Administrative details

EU PAS number

EUPAS13232

Study ID

46491

DARWIN EU® study

No

Study countries

☐ Sweden

Study description

THE STUDY DID NEVER START AND NO PATIENTS WERE ENROLLED. This is an open-ended, non-interventional, retrospective, drug utilization study which will assess data extracted from the Swedish National Quality Register regarding drug prescribing patterns, including any off-label use of PLENADREN. Data will be obtained from 2 registries within the Swedish National Quality Register, the National Patient Register (NPR, includes both inpatient and outpatient information) and the National Pharmaceutical Drug Register (NPDR). Data will be extracted from the registries after the launch of PLENADREN in Sweden (01 November 2012) and as soon as the number of patients treated with PLENADREN is estimated to be sufficient to perform an analysis, and will continue once yearly until the study is discontinued. PLENADREN is reported to be used off-label in adults for the treatment of the condition “adrenal fatigue”, which is not a medically distinct syndrome.

Study status

Finalised

Research institutions and networks

Institutions

Shire

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Institution

Contact details

Study institution contact

Call Center Shire ClinicalTransparency@shire.com

Study contact

ClinicalTransparency@shire.com

Primary lead investigator

Call Center Shire

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/11/2013

Actual: 20/11/2013

Study start date

Planned: 20/11/2013

Actual: 20/11/2013

Date of final study report

Planned: 20/11/2013

Actual: 20/11/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Shire

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is to monitor any off-label use of PLENADREN.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Open-ended, non-interventional, retrospective study, prescription event monitoring, case-series

Study drug and medical condition

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

HYDROCORTISONE

Medical condition to be studied

Adrenal insufficiency

Population studied

Short description of the study population

Patients treated with PLENADREN.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

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)

Estimated number of subjects

20

Study design details

Outcomes

Percentage of patients prescribed PLENADREN who are <18 years of age, andPercentage of patients receiving PLENADREN for reasons other than treatment of AI (Adrenal insufficiency), Assessment of physician prescribing patterns for PLENADREN.

Data analysis plan

A summary of the data incorporated in the analysis reports will be included in the annual Period Benefit-Risk Evaluation Report (PBRER) for PLENADREN.All continuous variables will be summarized using standard statistical measures (i.e number of observations, mean, standard deviation SD, median, minimum, and maximum). All categorical variables will be summarized in frequency tables. Demographic and baseline data, as well as disease and treatment

characteristics data, will be summarized using descriptive statistics. The primary and secondary endpoints of the study will be presented descriptively and summarized using 95% CIs. Subgroup data will also be presented descriptively.

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 sources (types)

Disease registry

Drug registry

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