

Post-authorisation safety study of NOCDURNA for the symptomatic treatment of nocturia due to idiopathic nocturnal polyuria: A multi-country cohort study using secondary data. (NOCDURNA PASS)

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Study

Ongoing

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/48154>

EU PAS number

EUPAS38365

Study ID

48154

DARWIN EU® study

No

Study countries

Denmark
Germany
Sweden

Study status

Ongoing

Research institution and networks

Institutions

Ferring Pharmaceuticals

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Christian Froesig

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual:

30/11/2020

Study start date

Planned:

01/07/2021

Actual:

01/07/2021

Data analysis start date

Planned:

01/08/2021

Date of interim report, if expected

Planned:

31/12/2021

Date of final study report

Planned:
11/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ferring Pharmaceuticals

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Retrospective study to assess the post-authorisation safety of NOCDURNA using longitudinal RWD. Also, since it is desirable to put these observations into context and characterise a population with similar indications who do not receive desmopressin, a similar number of patients receiving standard care for other lower urinary tract symptoms will be evaluated in order to inform NOCDUR safety and use.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

DESMOPRESSIN

Medical condition to be studied

Nocturia

Population studied

Age groups

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

7090

Study design details

Outcomes

To estimate the incidence rate of symptomatic hyponatraemia (defined as a recorded diagnosis of hyponatraemia) among patients treated with NOCDURNA, and patients with LUTS separately, overall and by subgroups of interest (including elderly patients, aged > 65 years). 1. Describe the demographic 2. Incidence rate of hyponatraemia requiring hospital intensive care 3. Incidence rate of hyponatraemia 4. Rate of mortality 5. Incidence rate of CV and venous thromboembolic events 6. Incidence rate of acute exacerbation of CHF 7. Patients adhering to the label 8. Adjustment for confounding 9. Treatment withdrawal of NOCDURNA

Data analysis plan

This is a multi-country, cohort study using secondary data collected from research databases and administrative national healthcare registries in selected European countries (Denmark, Germany and Sweden). Cohorts of patients using NOCDURNA or treatment of LUTS (new user) will be identified from existing data sources in each country of study. These data sources hold information on dispensed prescriptions, patient demographics and diagnoses. The LUTS contextual cohort will be comprised of patients based newly starting treatments associated with polyuria, receiving relevant standard care. For secondary

comparative analyses, the comparator group for NOCDURNA patients will be LUTS patients. In addition to the final study report, there will be annual interim reports on study progress and any emerging safety data. Both country-specific and pooled results (meta-analysis) will be presented in the final report, where data are available.

Data management

Data sources

Data source(s)

Danish registries (access/analysis)
National Prescribed Drugs Register / Läkemedelsregistret
German Pharmacoepidemiological Research Database

Data sources (types)

[Drug dispensing/prescription 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