ELMIRON: Observational Study for the Characterisation of Treatment Practice, Patients, and Symptom Load of Oral Pentosane Polysulfate Sodium for the Treatment of Interstitial Cystitis / Bladder Pain Syndrome

First published: 05/11/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44360

EU PAS number

EUPAS43996

Study ID

44360

DARWIN EU® study

No

Study countries

☐ France

Study description

The objective of this study is to characterise the patients treated with elmiron® and how elmiron® is used (e.g. age, diagnostic criteria for prescription, dosage, duration of treatment, reasons for stopping treatment, and co-treatment).

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 5 centres are involved in the study

Contact details

Study institution contact

Constanze Waltenberger

Study contact

contact@bene-gmbh.de

Primary lead investigator

Christian Saussine

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2021

Actual: 15/07/2021

Study start date

Planned: 30/06/2021

Actual: 15/09/2021

Data analysis start date

Planned: 31/12/2023

Actual: 04/11/2021

Date of interim report, if expected

Planned: 31/05/2022

Actual: 04/11/2021

Date of final study report

Planned: 31/03/2024

Actual: 04/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

bene-Arzneimittel GmbH

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

ID RCB: 2021-A00802-39

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

Data collection methods:

Primary data collection

Main study objective:

The objective of this study is to characterise the patients treated with elmiron® and how elmiron® is used (e.g. age, diagnostic criteria for prescription, dosage, duration of treatment, reasons for stopping treatment, and co-treatment). Primary objective = Characterisation of elmiron® treatment practice for the treatment of IC/BPS

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

Name of medicine

ELMIRON

Medical condition to be studied

Cystitis interstitial

Off label use

Population studied

Short description of the study population

Adult patients treated with elmiron® suffering from chronic interstitial cystitis

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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)

Special population of interest

Other

Special population of interest, other

Chronic interstitial cystitis

Estimated number of subjects

100

Study design details

Data analysis plan

ELMIRON is a non-comparative, exploratory study not involving the formal testing of any preformulated hypotheses. Parameters are summarised by appr.

key figures (number, percentage for categorical data, arithmetic mean, standard deviation, minimum, median, maximum, sample size for metric data). The Kaplan-Meier-Estimator used to model drug survival. Descriptive statistics are performed for all subjects and defined subgroups. The creation of additional subgroups is permissible. Differences between the groups are tested by the non-parametric Mann-Whitney Test and the χ^2 Test for significance in a purely exploratory fashion. The statistical analysis software Stata® is used for all statistical analyses.

Data management

Data sources

Data sources (types)

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