A Cross-sectional Study Among Healthcare Professionals in Canada to Assess Awareness and Knowledge of the Fibristal Additional Risk Minimization Measures

First published: 01/09/2020

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37710

EU PAS number

EUPAS36083

Study ID

37710

DARWIN EU® study

No

Study countries

Canada

Study description

This Cross-sectional study will assess Healthcare Professional's (HCPs) receipt and use of the Fibristal aRMMs, and knowledge of the key messages included in the materials developed as well as information in the December 2018 updated Canadian Product Monograph (CPM) for Fibristal. This study was cancelled before any data collection due to business reasons.

Study status

Finalised

Research institutions and networks

Institutions

ICON Commercialisation & Outcomes

Germany

Ireland

First published: 19/03/2010

Last updated: 05/07/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/04/2019

Actual: 21/04/2019

Study start date

Planned: 30/09/2020

Actual: 28/09/2020

Date of final study report

Planned: 30/06/2021

Actual: 28/09/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

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

CMO-EPI-WH-0618

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Assessment of awareness and knowledge of the fibristal additional risk minimization measures

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

aRMM evaluation (Safety)

Data collection methods:

Primary data collection

Main study objective:

This is a non-interventional, cross-sectional survey study to evaluate the effectiveness of the aRMMs for Fibristal among HCPs who prescribe Fibristal in Canada.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

A Cross-sectional Study Among Healthcare Professionals

Population studied

Short description of the study population

HCPs in Canada who prescribe Fibristal. The target population is the list of HCPs who were mailed the Fibristal aRMMs in the 1st quarter of 2019

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

150

Study design details

Outcomes

Assess levels of HCPs’ knowledge for the following: -The updated indication (restrict intermittent treatment to those women who are not eligible for surgery) and contraindication (Fibristal must not be used in women with history of/or active hepatic disease). -New requirements for liver function test monitoring. -Patient counseling. -Assess levels of receipt and reading of the Fibristal HCP Letter and Fibristal HCP Brochure, distribution of the Patient Alert Card, and counseling patients on the information in the Patient Alert Card, among HCPs who prescribe Fibristal. -Assess the primary source(s) from which HCPs learned about the core messages included in the Fibristal aRMMs. -Interpret composite variable on level of HCP

Data analysis plan

Survey results will be analyzed using SAS, most of the analyses are planned to be descriptive in nature. Results will be summarized in tables. Frequencies, percentages, and corresponding 95% confidence intervals (CIs) will be used to summarize the primary and secondary endpoints. For each knowledge-level question, the percentage of HCPs who answer each question correctly will be

calculated and assessed against an 80% (± 95% CI) target threshold for success.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

A list of HCPs who were mailed the Fibristal aRMMs in the 1st quarter of 2019

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