A Cross-sectional Study Among Patients in Canada to Assess Awareness and Knowledge of the Fibristal Patient Alert Card

First published: 01/09/2020

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS36199

Study ID

37707

DARWIN EU® study

No

Study countries

☐ Canada

Study description

This Cross-sectional study will assess patients' receipt and use of the Fibristal Patient Alert Card, and knowledge of the key messages included in Fibristal Patient Alert Card. 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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Study contact

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Primary lead investigator

Ahunna Ukah

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/04/2019

Actual: 21/04/2019

Study start date

Planned: 31/10/2020

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-0626

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Assessment of patients’ receipt and use of the Fibristal Patient Alert Card

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:

The overall objective of this study is to assess patients’ receipt and use of the Fibristal Patient Alert Card, and knowledge of the key messages included in Fibristal Patient Alert Card.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

A non-interventional, cross-sectional survey study to evaluate effectiveness

Population studied

Short description of the study population

Patients in Canada who have been treated with Fibristal. The target population will be derived primarily from patients treated by Healthcare Professionals who prescribe Fibristal.

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 patients’ knowledge for the following core message domains: - Potential for Fibristal to cause liver injury. - Signs and symptoms of liver problems. - What to do in case of signs and symptoms of liver problems. - Assess levels of receipt and use (e.g. read, carrying) of the Fibristal Patient Alert Card among patients who have received Fibristal. -Assess adherence of HCPs to counseling patients and to the requirement to order liver function tests, as reported by patients, in accordance with the recommendations in the aRMMs/CPM.

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 endpoints. For each knowledge level question, the percentage of patients who answer each question correctly will be estimated and assessed against a 70% (± 95% CI) target threshold for success.

Data management

Data sources

Data sources (types)

Patient surveys

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