Impact of tafamidis in Colombian patients diagnosed with ATTR-CA in quality of life during two year of follow up

First published: 06/11/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS105913

Study ID

108090

DARWIN EU® study

No

Study countries

Colombia

Study description

This study will be a non interventional, descriptive and longitudinal prospective with primary data collection that involves sites/investigators.
The patients have to be diagnosed before enrollment with ATTR-CA and prescribed with tafamidis following the the indications approved by National Institute for Drug and Food Vigilance (INVIMA) in Colombia.
The patients will be followed up from the index date untilpatient i) have deceased, ii) have decided to withdraw of the study, iii) have terminated of treatment, iv) have been lost to follow up, or, v) finalize the 24 months of following up. The index date will be defined as the date on which the first prescription of tafamidis is made.
There will be two sources of information.
Clinical and demographic information and death at the baseline will be abstracted from the medical record while the data related to hospitalizations, cardiovascular funcionality, quality of life will be collected directly from the patients using validated questionnaires and structured interviews.
Thus, in the case report form (CRF) will serve as a source document.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Juan Molina

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/07/2023

Actual: 19/10/2024

Study start date

Planned: 29/01/2024

Actual: 14/02/2024

Data analysis start date

Planned: 16/09/2024

Actual: 07/01/2025

Date of interim report, if expected

Planned: 15/01/2025

Date of final study report

Planned: 15/07/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer SAS

Study protocol

B3461112_Protocol ENG_V1_27JUL2023 Version final.pdf (742.07 KB)

B3461112_Protocol ENG_V3_06JUN2024 Version final.pdf (527.95 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Main study objective:

To describe the impact of tafamidis use in Colombian patients diagnosed with ATTR-CM on quality of life during two years of follow-up

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Tafamidis

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

TAFAMIDIS

Anatomical Therapeutic Chemical (ATC) code

(N07XX08) tafamidis

tafamidis

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

50

Study design details

Outcomes

- To describe the clinical and demographic characteristics of the patients at the moment of prescription of tafamidis;
- To determine the treatment patterns to manage ATTR-CM before Tafamidis prescription;
- To evaluate de frequency of hospitalization and its causes during the follow up period;
- To describe the use of cardiovascular devices during follow up of patients recruited in the study.

Data analysis plan

Frequencies and percentages will be reported for binary and categorical variables, while medians, means, standard deviation, and interquartile ranges (IQRs) will be reported for continuous variables, i.e. HRU.
Finally, it will be presented through a tabular display of summary statistics and will be complemented by the generation of graphs, such as histograms, boxplots, violin plots, density plots, scatterplots, depending on the nature of the

variable.
On the other hand, difference of means (Student or Welsch t-test) or medians (Wilcoxon or Kruskal-Wallis test) between subgroups will be considered (according to the variable distribution – normal or not), taking into account the sizes of these groups and trends in the behavior of the measures of centrality and dispersion

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)

Other

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No