

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

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Study

Planned

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 until patient 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 functionality, 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

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

Juan Reyes juanmanuel.reyes@pfizer.com

Study contact

juanmanuel.reyes@pfizer.com

Primary lead investigator

Juan Molina

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/07/2023

Study start date

Planned: 29/01/2024

Data analysis start date

Planned: 16/09/2024

Date of interim report, if expected

Planned: 30/07/2024

Date of final study report

Planned: 15/01/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer SAS

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 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

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, violinplots, 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

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No