Patient outcomes and clinical characteristics of ATTR-CM patients treated with tafamidis: A single center experience in Turkey - Study ATTREAL

First published: 01/07/2025

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000561

Study ID

1000000561

DARWIN EU® study

No

Study countries

Türkiye

Study description

The aim of this study is to describe the clinical characteristics and outcomes of patients with ATTR amyloid cardiomyopathy (ATTR-CM) treated with tafamidis at a single center in Turkey.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Actual: 07/01/2025

Study start date

Actual: 16/10/2025

Date of final study report

Planned: 31/12/2026

Study protocol

B3461126_Non-Interventional Study Protocol_V1_21MAY2025_Redacted.pdf
(12.34 MB)

B3461126_Non-Interventional Study Protocol_V2_16DEC2025_Redacted.pdf
(5.89 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

B3461126

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

This is a single-center, retrospective, non-interventional cohort study. Study data will be entered in CRF from individual patient medical records maintained in a single center in Turkey.

Main study objective:

To describe the rate of hospitalizations and emergency admissions due to chronic heart failure in the patients treated with Tafamidis

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VYNDAQEL

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

TAFAMIDIS

Anatomical Therapeutic Chemical (ATC) code

(N07XX08) tafamidis

tafamidis

Medical condition to be studied

Hereditary ATTR amyloid cardiomyopathy

Additional medical condition(s)

Transthyretin amyloid cardiomyopathy (ATTR-CM)

Population studied

Short description of the study population

Patients must meet the following inclusion criteria:

1) >18 years old at the time of diagnosis;

ii) diagnosed with hereditary or wild type ATTR-CM confirmed non-invasively (Tc99m PYP bone scintigraphy and/or SPECT-CT) in Samsun Education and Research Hospital – Cardiology Outpatient Clinic between January 2023 – January 2025;

iii) currently receiving or who have received tafamidis treatment for ATTR-CM;

iv) Availability of complete medical records, including baseline clinical characteristics, treatment outcomes, and follow-up data from electronic health record systems of hospital or physical patient files. Patients will be excluded if

participated in studies involving investigational drugs within 24 months before the index date.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

One centre involved in the diagnosis and management of patients affected by ATTR-CM will participate in the study. This Centre is selected according to their clinical and research expertise, in addition to the number of patients they are used to routinely caring for.

A clinical research organization (CRO) on behalf of Pfizer will support the regulatory and administrative procedures to get authorization and the operations at Centre needed for data collection.

The site Study Team, including the Principal Investigator and additional identified personnel (eg, research nurse, clinical study manager) will be trained on the protocol and planned study procedures, in addition to the use of the study-specific eCRF.

Original data, routinely collected by means of specific tools (eg, paper charts, electronic charts,) will be transferred to the eCRF by the Study Team in site.

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 source(s), other

Electronic health records and/or physical patient file

Data sources (types)

Electronic healthcare records (EHR)

Non-interventional study

Other

Data sources (types), other

paper/physical patient file

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

Unknown