Estudio de utilización de medicamentos para el tratamiento de la insuficiencia cardíaca (IDIAP-IC-2025) / Drug utilization study of treatments for heart failure (IDIAP-IC-2025)

First published: 11/12/2025

Last updated: 17/12/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000866

Study ID

1000000866

DARWIN EU® study

No

Study countries

Spain

Study description

Heart failure (HF) is usually classified according to left ventricular ejection fraction (LVEF), distinguishing between three phenotypes: HF with reduced LVEF (HFrEF), when it is ≤ 40%, HF with mildly reduced or intermediate LVEF (HFmrEF), when it is between 41-49%, and HF with preserved LVEF (HFpEF), if LVEF ≥ 50%. It is also common to use the New York Heart Association (NYHA) functional classification to describe the degree of HF, based on the severity of the patient's symptoms. The goal of HF treatment is to reduce mortality, reduce the risk of hospitalizations due to disease decompensation, and improve symptoms. The recommended pharmacological treatment based on scientific evidence varies depending on the HF phenotype. The objective of this study is to describe the clinical and sociodemographic characteristics of people diagnosed with HF and the pharmacological treatments used to manage the disease. We recently conducted this study in Catalonia using the regional SIDIAP database. Our goal is to replicate the same study with national data from BIFAP in order to compare the results.

Study status

Ongoing

Research institutions and networks

Institutions

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

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Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Contact details

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Study timelines

Date when funding contract was signed

Planned: 31/03/2025

Study start date

Planned: 30/06/2025

Actual: 01/12/2025

Data analysis start date
Planned: 01/09/2025

Date of final study report
Planned: 31/01/2027

Sources of funding

- No external funding

Study protocol

Protocolo IC-BIFAP_clean_V2.0_20250317.pdf (624.92 KB)

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

0167-2025-OBS

REec (Spanish Clinical Studies Registry)

Methodological aspects

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Descriptive population-based cohort study

Main study objective:

To describe sociodemographic and clinical characteristics of people with heart failure and the pharmacological treatment used

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Drugs for heart failure treatment

Medical condition to be studied

Heart failure with reduced ejection fraction

Heart failure with midrange ejection fraction

Heart failure with preserved ejection fraction

Population studied

Short description of the study population

Adults with diagnosis of heart failure registered in the Primary Care electronic records of 12 Autonomous Communities in Spain from 2018 to 2024.

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)

Estimated number of subjects

300000

Study design details

Setting

Primary Care of 12 regions of Spain covered by BIFAP database, with prevalent and incident diagnoses from 2018 to 2024.

Comparators

Not applicable

Outcomes

The variables that will be collected during patient follow-up in the study period are: exposure to drugs of interest used in the treatment of HF (treatment changes, persistence), hospitalizations due to HF decompensation (CMBD hospital discharge diagnoses), and all-cause mortality.

Hospitalizations due to decompensation prior to entry into the study cohort will be collected in order to analyze the background, as well as those that occur during the entire follow-up period of patients from the time they are included in the cohort. Hospitalizations due to HF decompensation will be defined as those with a diagnosis of HF and related symptoms (pulmonary edema, nonspecific hepatomegaly, cardiogenic shock, and nonspecific edema) that occur during the follow-up period. For both HF decompensations and all-cause mortality during follow-up, incidence rates will be calculated.

Data analysis plan

Population characteristics will be described using absolute frequency and percentage for categorical variables, and using mean and standard deviation (SD) and/or median and interquartile range (IQR) for continuous variables, depending on their distribution.

Incidence rates (IR) will be estimated for all-cause mortality and hospital admission due to disease decompensation. The risk of events between groups will be compared using the IR rate (IRR), both crude and adjusted for relevant variables. These values will be presented together with their point estimate and 95% confidence interval (CI).

The results will be presented comprehensively for the entire population, as well as stratified by sex.

Analytical methods will be used to control for confounding variables.

All analyses will be performed using version 4.2 or higher of the R statistical package.

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)

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

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