Prevalence, Incidence and Patient Characteristics of Chronic Heart Failure (CHF) and the Predicted Subtypes HFrEF(<40%), HFpEF(≥40%) in Japan and United States

First published: 07/05/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS40997

Study ID

45334

DARWIN EU® study

No

Study countries

Japan

Study description

The primary objective of this study is to estimate the prevalence of Japan and US CHF patients using large population based claims and EMR databases. The secondary objectives are to estimate the incidence of CHF patients in Japan and USA, in addition, comparison of CHF patient characteristics and treatment pattern in the two countries will be made. Furthermore, as an exploratory objective, we will estimate the ratio of HFrEF/HFpEF using predictive modeling (Desai et al Circ Cardiovasc Qual Outcomes. 2018) for comparison with previously published ratio using Japanese heart failure registry data (Tsuchihashi-Makana et al, Circ J 2013)

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

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Primary lead investigator

Yasuhisa Ono

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/01/2021

Actual: 09/03/2021

Study start date

Planned: 03/05/2021

Actual: 04/05/2021

Data analysis start date

Planned: 21/04/2022

Actual: 20/05/2021

Date of final study report

Planned: 22/12/2021

Actual: 10/01/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingehleim

Study protocol

NBI_CHF Prevalence_Protocol_Mar 1 2021_final v1.pdf (1.42 MB)

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

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to estimate the prevalence of Japan and US CHF patients using large population based claims and EMR databases. The secondary objectives are to estimate the incidence of CHF patients in Japan and USA, in addition, comparison of CHF patient characteristics and treatment pattern in the two countries will be made.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Cardiac failure

Population studied

Short description of the study population

The population will include all known heart failure patients within the available data sets from 2014 – 2019. The starting population are any patients included in the Japan Medical Data Center, Medical Data Vision or Optum database with any claims record or insurance registration record during the period of January 1, 2014 to end of data period.

Inclusion criteria – Prevalent CHF case:

1. A code indicating a confirmatory diagnosis of heart failure in JMDC, MDV or Optum database prior to December 31, 2019
2. For JMDC and MDV, ICD 10 codes to identify heart failure cases will be: cardiac edema (I50.0), chronic congestive heart failure (I50.0), right heart failure (I50.0),
insufficiency of left heart (I50.1), cardiac dyspnea (I50.1), acute cardiac failure (I50.9), cardiac failure (I50.9), chronic cardiac failure (I50.9), cardiogenic pulmonary
edema (I50.0), myocardial failure (I50.9), bi-ventricular failure (I50.9), right ventricular failure (I50.0).
3. For Optum, at least 2 outpatient diagnosis or 1 inpatient diagnosis will be identified as confirmed cases. The following ICD 9-CM codes in addition to ICD 10 codes above) will be used to identify the CHF population of interest. Congestive heart failure: 428.0, 428.1, 428.2, 428.3, 428.4, 428.9, Heart failure with hypertensive heart disease: 402.01, 402.11, 402.91, Heart failure with hypertensive and renal disease: 404.01, 404.03, 404.11, 404.13, 404.91, 404.93

Inclusion criteria – Incident CHF case:

All above codes to identify CHF population will be used for JMDC, MDV and Optum; an incident case will be defined as having no diagnosis of CHF in the

preceding 12 months of new CHF diagnosis. Thus, a patient must have at least 12 months of insurance registration data prior to the initial diagnosis date of CHF.

Exclusions:

1. < 18 years at study entry
2. Patients with missing or ambiguous age or gender information
3. Patients with diagnosis code with doubt flag (suspect diagnosis)

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)

Special population of interest

Other

Special population of interest, other

Heart failure patients

Estimated number of subjects

200.000

Study design details

Outcomes

Crude and standardized prevalence of heart failure in Japan and United States annually and cross year between years 2014 to 2019. Incidence of heart failure

Demographics of heart failure prevalent population

Data analysis plan

Primary outcome: prevalence Yearly prevalence over the study period will be calculated as the number of HF patients under follow up on the 30th January each year, divided by the total number of patients under follow up on the December 31st of each year from the JMDC and Optum denominator files. Prevelance will be presented as a crude measure as well as age and gender standardised to account for any changes in age distrubtion across the study period per 1000 persons with 95% confidence interval.

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)

Administrative healthcare records (e.g., claims)

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