Assessing the profile of CHF patients with redUced ejection fraction being managed in the pRimary care sectOr across GeRmany as well as the phArmacologic treatment these HF patients receive (AURORA-HF)

First published: 22/03/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12912

Study ID

39319

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The non-interventional AURORA-HF study is conducted in cooperation with General Practitioners (GPs) who are treating chronic heart failure (CHF) patients in Germany. Amendment 01 of the protocol resulted in a strong reduction in the patient number and study sites. As the objectives do not address safety topics, Novartis does not expect that the trial will add knowledge on the safety of the medicinal product. Hence the trial category assessment changed from PASS to Non-PASS.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

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Institution

Multiple centres: 999 centres are involved in the study

Contact details

Study institution contact

Novartis Clinical Disclosure Office

Trialandresults.registries@novartis.com

Study contact

Trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Office

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/02/2016

Study start date

Planned: 23/03/2016

Actual: 29/03/2016

Data analysis start date

Planned: 01/08/2019

Actual: 20/12/2019

Date of final study report

Planned: 15/07/2019

Actual: 17/09/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma GmbH

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

CLCZ696BDE02

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

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

AURORA-HF will provide a picture of HFrEF patients being managed in the primary care sector across Germany. It will describe the pharmacologic treatment HFrEF patients receive, the demographic and clinical features of patients who will be started on Sacubitril/Valsartan and the demographic and clinical features of patients, who will receive Sacubitril/Valsartan as long-term therapy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

SACUBITRIL

VALSARTAN

Medical condition to be studied

Cardiac failure chronic

Population studied

Short description of the study population

Chronic heart failure (CHF) patients in Germany.

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

Hepatic impaired

Immunocompromised

Renal impaired

Estimated number of subjects

13056

Study design details

Outcomes

– To describe the profile of patients initiated on Sacubitril/Valsartan as compared to conventionally treated patients – To describe the profile of Sacubitril/Valsartan patients who remain on Sacubitril/Valsartan therapy until the final visit (approx. 12 months) as compared to those who permanently stop Sacubitril/Valsartan therapy

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Data analysis plan

The data will be analyzed by Novartis and/or by the designated CRO. All data will be analyzed descriptively. Probability of remaining on treatment until month 12 will be modelled using logistic regression. The following baseline characteristics will be fitted in the model as factors in order to determine the baseline characteristics which best describe the profile of patients who will remain on treatment:– SBP (<110 mmHg, 110 – 120 mmHg, >120 mmHg)– Age (<75 years, ≥75 years)– Renal function (eGFR < 60, eGFR >= 60)– Concomitant medications– Beta-blocker (yes/no)– MRA (yes/no)– Diuretics (yes/no)– NYHA class (II, III/IV)– Hospitalization for HF within the year prior to enrollment

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

Data sources (types), other

Prospective patient-based data collection

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