Assessment of Real LIfe cAre – Describing EuropeaN Heart FailurE Management (ARIADNE)

First published: 21/06/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/36264

EU PAS number

EUPAS13835

Study ID

36264

DARWIN EU® study

No

Study countries

☐ Austria

- [ ] Belgium
- [ ] Bulgaria
- [ ] Cyprus
- [ ] Estonia
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Malta
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Russian Federation
- [ ] Slovakia
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom

Study description

This is an observational, European NIS with prospective collection of primary data. Data will be collected for two groups of HFrEF patients: symptomatic patients who receive the current individualized standard of care (SoC) for the treatment of CHF and patients for whom the physician has decided to prescribe sacubitril/valsartan. Switching between different CHF treatments (e.g. between SoC and sacubitril/valsartan) is allowed at any time as per decision of the investigator. Enrollment will start in each country when sacubitril/valsartan is available for clinical use. Overall the present NIS will enroll 6000 patients on

SoC and 6000 patients on sacubitril/valsartan across Europe.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Multiple centres: 999 centres are involved in the study

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

Study contact

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Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 28/07/2015

Study start date
Planned: 30/07/2016

Actual: 25/07/2016

Date of final study report
Planned: 31/12/2019

Actual: 27/01/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

LCZ696B3401-redacted_protocol_final.pdf(679.81 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

CLCZ696B3401

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Patient characterization in terms of demographics, medical history, HF status, comorbidity burden

Data collection methods:

Primary data collection

Main study objective:

To describe the demographic and clinical features of HFrEF patients managed in the outpatient sector and the diagnostic and pharmacological interventions they receive and the demographic and clinical features of patients for whom treating physician decided to start sacubitril/valsartan, the pattern of administration of this drug, the diagnostic and therapeutic interventions these patients receive

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

Chronic left ventricular failure

Population studied

Short description of the study population

The present study wil include consecutive HFrEF patients treated by office based cardiologists or selected primary care physicians across Europe.
Inclusion criteria:
1. Written informed consent provided by the patient or legal representative for participting in the study
2. Age 18 years or older
3. Patient with symptomatic CHF with a documented reduce left ventricular ejection fraction (LVEF) as assessed by clinical examination and any imaging technique performed anytime in the past

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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

Chronic left ventricular failure patients

Estimated number of subjects

12000

Study design details

Outcomes

- Descriptive analysis of baseline characteristics of patients initiated on sacubitril/valsartan and patients continued on SoC in outpatient sector - Descriptive analysis of profile of sacubitril/valsartan patients not reaching and maintaining target dose of 200mg twice daily in terms of demographics, medical history, HF status, comorbidity burden as compared with patients reaching target dose, - describe the overall HFrEF population managed in the outpatient sector in Europe- describe HF-treatment in the outpatient sector in Europe- describe the starting dose, titration and maintenance dose of sacubitril/valsartan in patients with different anamnestic and demographic characteristics- describe safety and tolerability features of sacubitril/valsartan in real-world HF patients

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Data analysis plan

Only descriptive data analyses will be carried out, supported by calculation of confidence intervals. No statistical testing will be performed. Analyses will be performed for the total sample and stratified by demographic, anamnestic and medical factors (e.g. sex, duration of HF, severity of HF, previous HF-treatment), using an adequate grouping. As appropriate, analysis of all endpoints will also be carried out after stratification according to CHF treatment during the observation period.

Documents

Study results

lcz696b3401p01--legacy-clinical-study-report_Redacted.pdf(534.29 KB)

Data management

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