Beta-blockers in patients with heart failure with reduced ejection fraction and concomitant chronic obstructive pulmonary disease: cardiovascular and respiratory outcomes

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000462

EU PAS number

EUPAS1000000462

Study ID

1000000462

DARWIN EU® study

No

Study countries

Sweden

Study description

Objective: To assess cardiovascular effectiveness and respiratory safety of beta-blocker treatment in patients with heart failure with reduced ejection fraction and concomitant chronic obstructive pulmonary disease

Study status

Ongoing

Research institutions and networks

Institutions

Karolinska Institutet

Sweden

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Institution | Educational Institution

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: 05/09/2024

Study start date

Actual: 24/09/2024

Data analysis start date

Actual: 26/09/2024

Date of final study report

Planned: 07/02/2025

Sources of funding

- EU institutional research programme
- Other public funding (e.g. hospital or university)

More details on funding

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Study protocol

BB in COPD_HARPER_2025-01-27.pdf(803.39 KB)

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:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Retrospective cohort study using data from the Swedish Heart Failure Registry and other national registers

Main study objective:

To assess cardiovascular effectiveness and respiratory safety of beta-blocker treatment in patients with heart failure with reduced ejection fraction and concomitant chronic obstructive pulmonary disease

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Beta-blockers (metoprolol, bisoprolol, carvedilol)

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

METOPROLOL

Anatomical Therapeutic Chemical (ATC) code

(C07) BETA BLOCKING AGENTS

BETA BLOCKING AGENTS

Medical condition to be studied

Chronic obstructive pulmonary disease

Heart failure with reduced ejection fraction

Population studied

Short description of the study population

Patients with heart failure with reduced ejection fraction (HFrEF) and concomitant chronic obstructive pulmonary disease (COPD) registered in the Swedish Heart Failure Registry

Age groups

Adult and elderly population (≥18 years)

Study design details

Setting

Patients with HFrEF and concomitant COPD registered in the Swedish Heart Failure Registry between July 2006 and December 2023 are included.

Comparators

Beta-blocker therapy vs no beta-blocker therapy

Outcomes

Primary safety outcome: total number of severe COPD exacerbations (5-years follow-up)

Primary effectiveness outcome: cardiovascular death and total number of heart failure hospitalisations (5-years follow-up)

Data management

Data sources

Data source(s)

Swedish Cause of Death Register

Sweden National Prescribed Drugs Register / Läkemedelsregistret

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Data source(s), other

Swedish National Patient Register (NPR)

Swedish Heart Failure Registry (SwedeHF)

Swedish Longitudinal Integrated Database for Health Insurance and Labour (LISA)

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

Yes

Data characterisation moment

after data extraction

after creation of study variables