Associations between Cardiac Resynchronization Therapy and Clinical Outcomes According to the Atrial Fibrillation Status in Patients with Heart Failure with Reduced Ejection Fraction

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000699

Study ID

1000000699

DARWIN EU® study

No

Study countries

Sweden

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Renzo Laborante

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2023

Study start date

Planned: 26/04/2025

Actual: 26/04/2025

Date of final study report

Planned: 05/10/2025

Study protocol

protocol_HARPER_CRT_AF_RL_0108.pdf (896.64 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 topic, other:

Evidence on the effectiveness of cardiac resynchronization therapy (CRT) in patients with heart failure with reduced ejection fraction (HFrEF) and atrial fibrillation (AF) is limited.

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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)

Swedish Cause of Death Register

Landspatientregisteret (National Patient Register)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

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Data source(s), other

- Swedish Heart Failure Registry (SwedeHF)

- Longitudinal Integrated Database for Health Insurance and Labour Market Studies (LISA)

- Swedish Implantable Cardioverter Defibrillator (ICD)- and Pacemaker- (PM) registry

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Data sources (types)

Administrative healthcare records (e.g., claims)

Death registry

Disease registry

Drug registry

Population registry

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