Applicability of past and ongoing steroidal and non-steroidal mineralocorticoid receptor antagonist trials in real-world patients with heart failure with reduced, mildly reduced, and preserved ejection fraction

First published: 04/08/2025

Last updated: 04/08/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000692

Study ID

1000000692

DARWIN EU® study

No

Study countries

Sweden

Study description

Steroidal mineralocorticoid receptor antagonists (sMRA) are core pillars in the treatment of patients with heart failure (HF) with reduced ejection fraction (HFrEF), while the evidence for HF with mildly reduced (HFmrEF) and preserved ejection fraction (HFpEF) is more ambiguous.
The novel non-steroidal MRAs (nsMRAs) present a new opportunity to target the MR in HF, with potentially lesser risk of adverse drug reactions such as hyperkalaemia.

We aim to assess the eligibility of a real-world HF population (Swedish Heart Failure Registry) to past and ongoing MRA trials to explore their generalisability, and to identify key inclusion and exclusion criteria to inform future trial design.

Study status

Ongoing

Research institutions and networks

Institutions

Karolinska Institutet

Sweden

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 29/01/2025

Actual: 29/01/2025

Study start date

Planned: 25/06/2025

Actual: 25/06/2025

Data analysis start date

Planned: 25/06/2025

Actual: 27/06/2025

Date of final study report

Planned: 28/02/2026

Sources of funding

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

More details on funding

This work is supported by the Horizon Europe programme (project number 101095479 - More-EUROPA), and the Swedish Heart and Lung Foundation (project number 20220680) to Dr. Gianluigi Savarese´s institution.
Dr. Benedikt Beer is supported by a grant of the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation; grant number 535014557).

Study protocol

MRA eligibility_Analysis plan_2025-07-21_2025-07-30 published HMA-EMA.pdf (1.04 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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

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

Assessment of applicability of RCTs on MRA in a real-world HF population based on enrolment criteria

Data collection methods:

Secondary use of data

Study design:

Cross-sectional study using Swedish quality registries in retrospect.

Main study objective:

We aim to assess the eligibility of a real-world HF population to past and ongoing MRA trials (RALES, TOPCAT, SPIRRIT-HFpEF, SPIRIT-HF, EMPHASIS-HF, FINEARTS-HF, FINALITY-HF, and REDEFINE-HF) to explore their generalisability, and to identify key inclusion and exclusion criteria to inform future trial design.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C03DA01) spironolactone

spironolactone

(C03DA04) eplerenone

eplerenone

(C03DA05) finerenone

finerenone

Medical condition to be studied

Heart failure with reduced ejection fraction

Heart failure with preserved ejection fraction

Additional medical condition(s)

Heart failure with mildly reduced ejection fraction

Population studied

Short description of the study population

Real-world patients with heart failure in the Swedish Heart Failure Registry (SwedeHF) with a registration in 2017-2023.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)

- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Frail population

Hepatic impaired

Renal impaired

Study design details

Setting

Country: Sweden

Time: 2017-2023

Care setting: in-hospital & specialised outpatient care

Condition: all HF phenotypes

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

Sweden National Prescribed Drugs Register / Läkemedelsregistret

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Data source(s), other

Swedish Heart Failure Registry (SwedeHF)

Swedish National Patient Register (NPR)

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

Data sources (types)

Administrative healthcare records (e.g., claims)

Death registry

Disease registry

Drug prescriptions

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

Data characterisation moment

after data extraction

after creation of study variables