# A multicenter, randomized, double-blind, double-dummy, parallel-group, active-controlled study to evaluate the efficacy and safety of finerenone compared to eplerenone on morbidity and mortality in patients with chronic heart failure and reduced ejection fraction after recent heart failure decompensation and additional risk factors, either type 2 diabetes mellitus or chronic kidney disease or both.

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Demonstrate the superiority of finerenone to eplerenone in delaying time to first occurrence of the compositeendpoint, defined as cardiovascular (CV) death or hospitalization for heart failure (HF), in patients withCHF (NYHA class II-IV) and reduced...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Heart failures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON44143

**Source**
ToetsingOnline

**Brief title**
FINESSE-HF

## Condition

- Heart failures
- Glucose metabolism disorders (incl diabetes mellitus)
- Renal disorders (excl nephropathies)

**Synonym**
Chronic heart failure; decompensation cordis

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Bayer
**Source(s) of monetary or material Support:** Bayer HealthCare AG

## Intervention

**Keyword:** Chronic Heart Failure, Heart Failure with reduced ejection fraction (HFREF)

## Outcome measures

### Primary outcome

Demonstrate the superiority of finerenone to eplerenone in delaying time to

first occurrence of the composite

endpoint, defined as cardiovascular (CV) death or hospitalization for heart

failure (HF), in patients with

CHF (NYHA class II-IV) and reduced ejection fraction after recent heart failure

decompensation who have

additional risk factors, i.e. type 2 diabetes mellitus (T2DM) and/or chronic

kidney disease (CKD).

### Secondary outcome

The secondary objectives are to determine the superiority of finerenone to

eplerenone with regard to the following:

Total number of hospitalizations (or equivalent) for HF Delaying the time to

first hospitalization (or equivalent)

for HF Delaying the time to all-cause mortality Delaying the time to first

occurrence of composite renal

endpoint: onset of kidney failure, or sustained decrease in estimated

glomerular filtration rate (eGFR) >=40%

relative to baseline over at least 4 weeks, or renal death.

# Study description

**Background summary**

Current treatment for Heart Failure (HF) consists of angiotensin-converting enzyme inhibitors, angiotensin
receptor blockers and beta-blockers. Despite their use, aldosterone and cortisol levels remain inappropriately
elevated in patients with signs and symptoms of chronic heart failure (CHF). This may contribute to cardio-renal
dysfunction. The deleterious neurohormonal profile and the observation that mineralocorticoid receptor
antagonists (MRAs) significantly reduce morbidity and mortality in HF has prompted studying the utility of
MRAs in WCHF (Worsening Chronic Heart Failure). Finerenone is a novel non-steroidal MRA. Efficacy and safety of finerenone will be
investigated in patients with CHF and either type 2 diabetes mellitus or chronic kidney disease (CKD) or
both in comparison to eplerenone.

**Study objective**

Demonstrate the superiority of finerenone to eplerenone in delaying time to first occurrence of the composite
endpoint, defined as cardiovascular (CV) death or hospitalization for heart failure (HF), in patients with
CHF (NYHA class II-IV) and reduced ejection fraction after recent heart failure decompensation who have
additional risk factors, i.e. type 2 diabetes mellitus (T2DM) and/or chronic

kidney disease (CKD).

### Study design

A randomized, double-blind, dubbel-dummy, parralel-group, multi-center, event driven study.

### Intervention

Treatment with 10 or 20 mg finerenon or 25 mg eplerenon every other day or 25 mg eplenerone (daily) or 50 mg epleneron (daily).

### Study burden and risks

Finerenone may have some therapeutic benefit, however this cannot be guaranteed. Patients are at risk of experiencing side effects.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

• Women of childbearing potential can only be included in the study if a pregnancy test is negative at Screening and if they agree to use adequate contraception. Adequate contraception is defined as any combination of at least 2 effective methods of birth control, of which at least one is a physical barrier (e.g. condoms with hormonal contraception or implants or combined oral contraceptives, certain intrauterine devices). Women are considered post-menopausal and not of childbearing potential if they have had 12 months of natural (spontaneous) amenorrhea with an appropriate clinical profile (e.g. age appropriate, history of vasomotor symptoms) or 6 months of spontaneous amenorrhea with serum follicle-stimulating hormone (FSH) levels >40 mIU/mL [for US only: and estradiol <20 pg/mL] or have had surgical treatment such as bilateral tubal ligation, bilateral ovariectomy, or hysterectomy.;• Diagnosis of CHF, NYHA class II-IV, and documented ejection fraction of <=40%;• Unscheduled emergency presentation to emergency services (outpatient or hospital, including the emergency department ) due to signs and/or symptoms of HF decompensation in the 2 weeks preceding randomization (considered as index event);• Administration of intravenous (IV) decongestive therapy at any time during presentation and/or admission to emergency services for the treatment of the index event;• BNP >400 pg/mL or NT-proBNP >1200 pg/mL in sinus rhythm, and BNP >600 pg/mL or NT-proBNP >1800 pg/mL in atrial fibrillation, at any time starting with the index event, at the latest at screening; ; BNP values are not applicable for subjects taking angiotensin receptor-neprilysin inhibitors (ARNIs);• Type 2 diabetes mellitus (T2DM) in their medical history or at screening ;and/or;Chronic kidney disease (CKD) with moderately reduced kidney function, defined as an estimated glomerular filtration rate (eGFR) between 30 and 60 mL/min/1.73 $m^2$ at screening (calculated using the locally approved and validated equation); one reassessment allowed

## Exclusion criteria

• Acute de-novo heart failure or acute inflammatory heart disease, e.g. acute myocarditis, within 3 months prior to randomization;• Acute coronary syndrome, including unstable angina, non-ST segment elevation myocardial infarction (NSTEMI) or ST segment elevation myocardial infarction (STEMI), or major CV surgery including coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), implantation of a cardiac resynchronization therapy(CRT) device or cardiac contractility modulation (CCM) device, or carotid angioplasty within 3 months prior to randomization;• Stroke or transient ischemic cerebral attack within 3 months prior to randomization;• Cardiogenic shock at randomization, prior to first intake of study drug;• Any primary cause of HF scheduled for surgery , e.g. valve disease such as severe aortic stenosis;• History of heart transplant or need for heart transplantation; presence or need of left ventricular assist device

# Study design

## Design

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|---|---|
| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 141 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Finerenone |
| Generic name: | Bay 94-8862 |
| Product type: | Medicine |
| Brand name: | Inspra |
| Generic name: | eplerenone |
| Registration: | Yes - NL intended use |

# Ethics review

Approved WMO

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|---|---|
| Date: | 30-09-2015 |
| Application type: | First submission |
| Review commission: | METC Maxima Medisch Centrum (Veldhoven) |

Approved WMO

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|---|---|
| Date: | 03-11-2015 |
| Application type: | First submission |
| Review commission: | METC Maxima Medisch Centrum (Veldhoven) |
| Approved WMO Date: | 27-01-2016 |
| Application type: | Amendment |
| Review commission: | METC Maxima Medisch Centrum (Veldhoven) |
| Approved WMO Date: | 08-02-2016 |
| Application type: | Amendment |
| Review commission: | METC Maxima Medisch Centrum (Veldhoven) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2015-002168-17-NL |
| CCMO | NL55097.015.15 |