A multicenter, randomized, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of finerenone on morbidity and mortality in participants with heart failure (NYHA II-IV) and left ventricular ejection fraction >= 40% (LVEF >= 40%).

Published: 18-05-2020
Last updated: 09-04-2024

To demonstrate the superiority of finerenone to placebo in reducing the rate of the composite CV endpoint.To determine superiority of finerenone to placebo for each secondary endpointTo assess the safety and tolerability of finerenone

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON52867

Source
ToetsingOnline

Brief title
FINEARTS-HF

Condition

- Heart failures

Synonym
heart failure, heart's inability to pump efficiently

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Finerenone, Heart Failure, left ventricular ejection fraction

Outcome measures

Primary outcome

To determine whether finerenone is superior to placebo in reducing the rate of the composite CV endpoint.

Cardiovascular (CV) death and total (first and recurrent) HF events (HHF or urgent HF visit) in HF patients (New York Heart Association [NYHA] class II-IV) and LVEF >=40%.

Secondary outcome

•. Time to total (first and recurrent) HF events

• Improvement in NYHA class from Baseline to Month 12

• Change from baseline to Month 6, 9 and 12 in Total Symptom Score (TSS) of the KCCQ.

• Time to first occurrence of composite renal endpoint: sustained decrease in estimated glomerular filtration rate (eGFR) >=50% relative to baseline over at least 4 weeks, or sustained eGFR decline <15ml/min/1.73m2 or initiation of dialysis or renal transplantation.

• Time to all-cause mortality.

Study description

Background summary

A study to gather information on the influence of study drug finerenone on the number of deaths and hospitalizations in participants with heart failure.

Study objective

To demonstrate the superiority of finerenone to placebo in reducing the rate of the composite CV endpoint.
To determine superiority of finerenone to placebo for each secondary endpoint
To assess the safety and tolerability of finerenone

Study design

Multicenter, randomized, double-blind, parallel-group, placebo-controlled study.

Intervention

Finerenone of placebo;
1. Participants with an eGFR <=60 mL/min/1.73m² starting dose 10 mg OD. Maximum dose 20 mg and minimum dose 10 mg OD.
2. Participants with an eGFR >60 mL/min/1.73m² starting dose 20 mg OD. Maximum dose 40 mg and minimum dose 10 mg OD.

Study burden and risks

More information on the safety as well as burden and risks is available in the PIIC and the IB.
In addition there could be potential side effects or potential burden due to the procedures done in this study.
In our opinion the impact on the patient is minimal. If they are perceived as disadvantageous for the patient, the patient can always stop the study without giving any reason and without experiencing any consequences for medical care.

Contacts

Public
Bayer

Siriusdreef 36
Hoofddorp 2132 WT
NL
Scientific
Bayer

Siriusdreef 36
Hoofddorp 2132 WT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Participant (male or female) must be aged 40 years and older, at the time of signing the informed consent.
2. Diagnosis of heart failure with NYHA class II-IV, ambulatory or hospitalized primarily for heart failure.
3. On diuretic treatment for at least 30 days prior to randomization.
4. Documented LVEF of >=40% measured by any modality within the last 12 months.
5. Structural heart abnormalities based on any local imaging measurement within the last 12 months, defined by at least one of the following findings: LAD >=3.8cm, LAA >=20cm2, LAVI >30 mL/m2, LVMI >=115 g/m2 (*)/ 95 g/m2 (*), septal thickness or posterior wall thickness >=1.1 cm.
6. NT-proBNP >=300 pg/mL (BNP >= 100 pg/mL) in SR and patient does not have an ongoing diagnosis of paroxysmal atrial fibrillation or NT-proBNP >=900 pg/mL (BNP >= 300 pg/mL) in AF or if patient has an ongoing diagnosis of paroxysmal atrial fibrillation obtained at the following time:
- Within 90 days prior to randomization if patient had been hospitalized for HF requiring initiation or change in HF therapy or if patient had an urgent visit for HF requiring intravenous (IV) diuretic therapy, both within 90 days prior to randomization

OR
- Within 30 days prior to randomization if patient has not been hospitalized for HF nor had an urgent HF visit within the past 90 days.
7. Women of childbearing potential can only be included in the study if a pregnancy test is negative at screening and baseline and if they agree to use adequate contraception which is consistent with local regulations regarding the methods for contraception for those participating in clinical trials.

Exclusion criteria

1. eGFR < 25 mL/min/1.73 m² at either screening or randomization visit.
2. Serum/plasma potassium >5.0 mmol/L at either screening or randomization visit.
3. Acute inflammatory heart disease, e.g. acute myocarditis, within 90 days prior to randomization
4. Myocardial infarction or any event which could have reduced the ejection fraction within 90 days prior to randomization
5. Coronary artery bypass graft surgery in the 90 days prior to randomization
6. Percutaneous coronary intervention in the 30 days prior to randomization
7. Stroke or transient ischemic cerebral attack within 90 days prior to randomization
8. Probable alternative cause of participants* HF symptoms that in the opinion of the investigator primarily accounts for patient*s dyspnea such as significant pulmonary disease, anemia or obesity. Specifically, patients with the below are excluded:
- Severe pulmonary disease requiring home oxygen, or chronic oral steroid therapy
- History of primary pulmonary arterial hypertension
- Hemoglobin < 10 g/dl*
- Valvular heart disease considered by the investigator to be clinically significant
- BMI > 50 kg/m2 at screening
9. SBP >=160 mmHg if not on treatment with >=3 blood pressure lowering medications or >=180 mmHg irrespective of treatments, on 2 consecutive measurements at least 2-minute apart, at screening or at randomization

Study design

Design

Study phase: 3

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-10-2020
Enrollment:	73
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Finerenone
Generic name:	Bay-94-8862

Ethics review

Approved WMO Date:	18-05-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-07-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-08-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	14-08-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-09-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-09-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-10-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-11-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-02-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-02-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-03-2021
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-05-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-06-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-02-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-02-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-06-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-07-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-09-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	13-01-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-07-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-01-2024
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-01-2024
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2020-000306-29-NL
CCMO	NL73605.056.20