A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study to investigate the efficacy and safety of finerenone, in addition to standard of care, on the progression of kidney disease in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease

Published: 26-08-2015
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Demonstrate whether, in addition to standard of care (SoC), finerenone is superior to placebo in delaying the progression of kidney disease, as measured by the composite endpoint of time to first occurrence of kidney failure, a sustained decrease of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON47518

Source
ToetsingOnline

Brief title
FIDELIO-DKD

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Nephropathies

Synonym
kidney disease of diabetes; diabetic kidney Disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Diabetes mellitus type II related kidney disease, Diabetic kidney disease

Outcome measures

Primary outcome

The primary objective of this study is to:

Demonstrate whether, in addition to standard of care (SoC), finerenone is superior to placebo in delaying the progression of kidney disease, as measured by the composite endpoint of time to first occurrence of kidney failure, a sustained decrease of eGFR * 40% from baseline over at least 4 weeks or renal death.

Secondary outcome

The secondary objectives of this study are to determine whether finerenone, in addition to SoC, compared to placebo:

- Delays the time to first occurrence of the following composite endpoint: CV death or non-fatal CV events (i.e. non-fatal myocardial infarction, non-fatal

stroke, hospitalization for heart failure)

- Delays the time to all-cause mortality

- Delays the time to all-cause hospitalization

- Change in urinary albumin-to-creeatine ratio (UCAR) from baseline to month 4

- Time to first occurrence of the following composite endpoint: onset of kidney

failure, a sustained decrease in estimated glomerular filtration rate

Study description

Background summary

Individuals with diabetic kidney disease (DKD) are at elevated risk of cardiovascular morbidity and mortality, as well as progression of kidney disease. An inappropriate release of aldosterone contributes to the target organ damage found in conditions such as heart failure, chronic kidney disease and hypertension. Blockade of the action of aldosterone has demonstrated benefit in different forms of cardiovascular disease. Results from short-term studies show that treatment with mineralocorticoid receptor antagonists in addition to renin-angiotensin system (RAS) blockade improves albuminuria, but long-term outcome studies are lacking.

Finerenone, a potent and selective mineralocorticoid receptor blocker, is proposed to address the unmet medical needs in the DKD population, by providing protection against the development or recurrence of cardiovascular disease, as well as the progression of kidney disease, when added to current standard of care therapy with a RAS inhibitor.

Study objective

Demonstrate whether, in addition to standard of care (SoC), finerenone is superior to placebo in delaying the progression of kidney disease, as measured

by the composite endpoint of time to first occurrence of kidney failure, a sustained decrease of eGFR * 40% from baseline over at least 4 weeks or renal death.

Study design

A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven study

Intervention

10 mg or 20 mg finerenone once a day (depending on the eGFR) compared to a placebo .

Study burden and risks

Two screening visits, and up to 4 study visits in the first 6 months and thereafter visits every 4 months until the end of the study

Blood samples at each study visit.

Urine sample collection at specific visits (3 samples collected over 3 days)

Two questionnaires to complete at specific visits. EQ- 5D-5L - 2 pages in length and KDQL consists of 36 questions.

Physical Examination at specific visits.

ECG assessment at specific visits.

Some patients may need to modify current medication before entering the study.

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

Contacts

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Scientific

Bayer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Men or women aged 18 years and older. The lower age limit may be higher if legally required in the participating country.
- Women of childbearing potential can only be included in the study if a pregnancy test is negative at the Screening Visit 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 child bearing potential if they have had 12 months of natural (spontaneous) amenorrhea with an appropriate clinical profile (e.g. age appropriate) or 6 months of spontaneous amenorrhea with serum FSH levels > 40 mIU/mL [for US only: FSH levels > 40 mIU/mL and estradiol < 20 pg/mL] or have had surgical treatment such as bilateral tubal ligation, bilateral ovarectomy, or hysterectomy.
- Subjects with type 2 diabetes mellitus as defined by the American Diabetes Association
- Subjects with a clinical diagnosis of DKD based on either of the following criteria at the Run-in and Screening Visit:
* Persistent high albuminuria defined as UACR of * 30 mg/g (* 3.4 mg/mmol) but < 300 mg/g (< 33.9 mg/mmol) in 2 out of 3 first morning void samples and eGFR * 25 but < 60 mL/min/1.73 m2 and presence of diabetic retinopathy in the medical history
OR
* Persistent very high albuminuria defined as UACR of * 300 mg/g (* 33.9 mg/mmol) in 2 out of 3 first morning void samples and eGFR * 25 but < 75 mL/min/1.73 m2
- Prior treatment with ACEIs and ARBs as follows:

* For at least 4 weeks prior to the Run-in Visit, subjects should be treated with either an ACEI or ARB, or both
* Starting with the Run in Visit, subjects should be treated with only an ACEI or ARB
* For at least 4 weeks prior to the Screening Visit, subjects should be treated with the maximum tolerated labeled dose (but not below the minimal labeled dose) of only an ACEI or an ARB (not both) preferably without any adjustments to dose or choice of agent or to any other antihypertensive or antiglycemic treatment
- Serum potassium * 4.8 mmol/L at both the Run-in and the Screening Visit

Exclusion criteria

- Known significant non-diabetic renal disease, including clinically relevant renal artery stenosis
- HbA1c >12% (> 108 mmol/mol) at the Run-in Visit or Screening Visit
- Uncontrolled arterial hypertension with mean sitting systolic blood pressure (SBP) * 170 mmHg or mean sitting diastolic blood pressure (DBP) * 110 mmHg at the Run in Visit or mean sitting SBP * 160 mmHg or mean sitting DBP * 100 mmHg at the Screening Visit
- Subjects with a clinical diagnosis of chronic heart failure with reduced ejection fraction (HFrEF) and persistent symptoms (New York Heart Association class II-IV) at the Run in Visit (class 1A recommendation for MRAs)
- Dialysis for acute renal failure within 12 weeks prior to the Run-in Visit
- Renal allograft in place or a scheduled kidney transplant within the next 12 months from the Run in Visit

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: Recruitment stopped

Start date (anticipated):	09-11-2015
Enrollment:	147
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	26-08-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-09-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-01-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	15-01-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	20-04-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	04-05-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO Date:	27-09-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	04-10-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-11-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	28-11-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	25-04-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	08-06-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	20-06-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	29-06-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-10-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	

Date:	17-10-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	30-10-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	02-11-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	08-12-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-12-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	02-02-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-04-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	01-05-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	06-07-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	

Date:	23-07-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	30-07-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	19-09-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	27-09-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	27-05-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	05-06-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-08-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	22-08-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	24-10-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	

Date:	25-10-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	16-03-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	02-04-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	28-04-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	13-05-2020
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	EUCTR2015-000990-11-NL
CCMO	NL54196.015.15