An 18-month, open-label, single-arm safety extension study of an age-and bodyweight-adjusted oral finerenone regimen, in addition to an ACEI or ARB, for the treatment of children and young adults from 1 to 18 years of age with chronic kidney disease and proteinuria

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This study has been transitioned to CTIS with ID 2023-504885-50-00 check the CTIS register for the current data. A study to learn more about how safe the study treatment finerenone is inlong-term use when taken with an ACE inhibitor or angiotensin...

Ethical review	Approved WMO
Status	Pending
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON56223

Source
ToetsingOnline

Brief title
FIONA OLE

Condition

- Nephropathies

Synonym
chronic kidney disease, chronic kidney disease with proteinuria

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Chronic kidney disease, pediatric study, proteinuria

Outcome measures

Primary outcome

The main objective is to demonstrate that finerenone in addition to an

ACEI or ARB is safe when given long-term:

1. Number of participants with treatment emergent adverse events

(TEAEs)

2. Change in serum potassium levels from baseline to Day 540±7

3. Change in systolic blood pressure (SBP) from baseline to Day 540±7

Secondary outcome

The secondary objective is to assess the long-term treatment effects on

proteinuria and kidney function of finerenone in addition to standard of

care:

1. Change in urinary protein-to-creatinine ratio (UPCR) and urinary

albumin-to-creatinine ratio (UACR) from baseline to Day 540±7

2. Change in glomerular filtration rate (eGFR) from baseline to

Day 540±7

Study description

Background summary

Researchers are looking for a better way to treat children who have chronic kidney disease (CKD), which is long-term kidney disease, and proteinuria, a condition in which a person*s kidneys leak protein into the urine.
The kidneys filter waste and fluid from the blood to form urine. In children with
CKD, the kidney*s filters do not work as well as they should. This can lead to accumulation of waste and fluid in the body and proteinuria. CKD can lead to other medical problems, such as high blood pressure, also known as hypertension. Vice versa, hypertension and proteinuria can also contribute to worsening of CKD. Therefore, the treatment of CKD aims to control blood pressure and proteinuria. There are treatments available for doctors to prescribe
to children with CKD and hypertension and/or proteinuria. These include *angiotensin-converting enzyme inhibitors* (ACEI) and *angiotensin receptor blockers* (ARB). Both ACEI and ARB can improve kidney function by helping the renin-angiotensin-aldosterone system (RAAS) to work normally. The RAAS is a system that works with the kidneys to control blood pressure and the balance of fluid and electrolytes in the blood. In people with CKD, the RAAS is often too active, which can stop the kidneys from working properly and cause hypertension and proteinuria. However, ACEI or ARB treatment alone does not work for all patients with CKD as they only target the angiotensin part of the reninangiotensin-
aldosterone system.
The study treatment, finerenone, is expected to help control RAAS overactivation together with an ACEI or ARB.
So, the researchers in this study want to learn more about whether finerenone given in addition to either an ACEI or ARB can help their kidney function.

Study objective

This study has been transitioned to CTIS with ID 2023-504885-50-00 check the CTIS register for the current data.

A study to learn more about how safe the study treatment finerenone is in long-term use when taken with an ACE inhibitor or angiotensin receptor blocker over 18 months of use in children and young adults from 1 to 18 years of age with chronic kidney disease and proteinuria

Study design

An 18-month, open-label, single-arm safety extension study of an age-and

bodyweight-adjusted oral finerenone regimen, in addition to an ACEI or ARB, for the treatment of children and young adults from 1 to 18 years of age with chronic kidney disease and proteinuria

Intervention

BAY 94-8862 granules 3.4% Granules for oral suspension
BAY 94-8862 20 mg Coated tablet
BAY 94-8862 10 mg Coated tablet

Study burden and risks

There are 13 visits (screening/randomization and close out and regular visits
- the patient is asked 5 times to complete either 1 or 2 questionnaires.
- The patient is asked to submit urine 11 times
- The patient is asked to keep a handbook/diary from randomization
- The patient is not allowed to consume products containing grapefruit and St. John's wort
- During each visit vital signs are checked
- weight and height are determined during approximately half of the visits
All visits druing the entire study study will take approximately 21 hours.
Measurements
Vital signs: pulse rate, no risks
vital signs blood pressure: no risk, possible discomfort around the arm due to the blood presssure cuff
Body weight and height no risk
Blood draws: risks: pain, bruising, feeling faint or dizzy, infection
urine collection: no risk
ECG: risk: skin irritation
ECHO: no risk
BAY 94-8862 may have a therapeutic benefit, however this cannot be guaranteed. patients are at risk of side effects.

Contacts

Public
Bayer

Siriusdreef 36
Hoofddorp 2130AB
NL
Scientific
Bayer

Siriusdreef 36
Hoofddorp 2130AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

1. Participants must be >=1 year to 18 years of age, at the time of signing the informed consent/assent. 2. Prior participation in the finerenone Phase 3 study FIONA (19920) and not permanently discontinued from treatment by the end of treatment (EoT) visit in FIONA. 3. Participants must have a clinical diagnosis of chronic kidney disease (CKD) at Visit 1 which is defined as - CKD stages 1-3 (estimated glomerular filtration rate [eGFR] >=30 mL/min/1.73m^2) for children >=1 year to <19 years of age at FIONA EoT and at Visit 1 4. Treated with an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) at optimized doses defined as maximally tolerable doses within the recommended dose range according to guidelines on blood pressure (BP) management, unchanged for at least 30 days prior to Visit 1. 5. K+ <=5.0 mmol/L for children >=2 years of age at both FIONA EoT and Visit 1, and <=5.3 mmol/L for children <2 years of age at both FIONA EoT and Visit 1 6. Participant is able to receive enteral feeding (solid food, bottle or cup fed, feeding through nasogastric or gastric feeding tubes) with or without breastfeeding.

Exclusion criteria

1. Planned urological surgery expected to influence renal function 2. Patients who are candidates for renal transplantation, i.e., a kidney transplantation scheduled within the study time frame 3. Systemic hypertension Stage 2 defined

according to institutional guidelines on BP management at Visit 1. 4. Systemic hypotension defined as symptomatic hypotension or a mean systolic BP below the 5th percentile for age, sex and height but no lower than 80 mmHg for participants <18 years and symptomatic hypotension or a mean systolic blood pressure (SBP) <90 mmHg in participants >=18 years at Visit 1. 5. Known hypersensitivity to the study treatment (active substance or excipients) 6. Severe hepatic insufficiency defined by e.g. Child-Pugh C or analogous scores. 7. Participants with immune-mediated CKD using rituximab, cyclophosphamide, abatacept, or prolonged high-dose glucocorticoids (defined as >= 0.5 mg/kg/day of prednisolone or equivalent) for more than 7 days. 8. Concomitant therapy with a mineralocorticoid receptor antagonist (MRA) (eplerenone, spironolactone, esaxerenone, canrenone), any renin inhibitor (aliskiren, enalkiren, remikiren), any sodium-glucose co-transporter-2 (SGLT2) inhibitor (SGLT2i), sacubitril/valsartan combination (ARNI), or potassium-sparing diuretic (amiloride, triamterene) 9. Concomitant therapy with both ACEI and ARBs together 10. Concomitant therapy with strong cytochrome P450 isoenzyme 3A4 (CYP3A4) inhibitors, moderate or strong CYP3A4 inducers 11. Previous assignment to treatment during this study 12. Simultaneous participation in another interventional clinical study (e.g., Phase 1 to 4 clinical studies). 13. Any suspected (S)AE related to the study intervention which led to permanent discontinuation of study intervention during the FIONA study 14. Pregnant or breastfeeding or intention to become pregnant during the study

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	08-11-2022
Enrollment:	2
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Finerenone
Generic name:	BAY 94-8862
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	17-08-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-10-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-02-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-03-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-04-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-07-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-08-2023
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-09-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-09-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-10-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EU-CTR	CTIS2023-504885-50-00
EudraCT	EUCTR2021-002905-89-NL
CCMO	NL81933.091.22