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

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 year to 18 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Participants must be ≥1 year to 18 years of age, at the time of signing the informed consent/assent.
- 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.
- 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
- 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.
- 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
- Participants who have reached legal age of consent: Capable of giving signed informed consent.
- 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:

- Planned urological surgery expected to influence renal function
- Patients who are candidates for renal transplantation, i.e., a kidney transplantation scheduled within the study time frame
- Systemic hypertension Stage 2 defined according to institutional guidelines on BP management at Visit 1.
- 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.
- Known hypersensitivity to the study treatment (active substance or excipients)
- Severe hepatic insufficiency defined by e.g. Child-Pugh C or analogous scores.
- Participants using rituximab, cyclophosphamide, abatacept, or intravenous glucocorticoids
- 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)
- Concomitant therapy with both ACEI and ARBs together
- Concomitant therapy with strong cytochrome P450 isoenzyme 3A4 (CYP3A4) inhibitors, moderate or strong CYP3A4 inducers
- Previous assignment to treatment during this study
- Simultaneous participation in another interventional clinical study (e.g., Phase 1 to 4 clinical studies).
- Any suspected (serious) adverse event related to study intervention which led to permanent discontinuation during the FIONA study.
- Pregnant or breastfeeding or intention to become pregnant during the study

Conditions & Interventions

Interventions:
DRUG: Finerenone (Kerendia, BAY94-8862)
Conditions:
Chronic Kidney Disease, Proteinuria, Children

More Information

Description:
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 help improve kidney function by reducing the activity

enzyme inhibitors" (ACEI) and "angiotensin receptor blockers" (ARB). Both ACEI and ARB can help improve kidney function by reducing the activity of the renin-angiotensin-aldosterone system (RAAS). 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 impair the ability of the kidneys to work 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 renin-angiotensin-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. The main purpose of this study is to learn how safe the treatment is when used of finerenone in addition to an ACEI or ARB in long-term. To see how safe the treatment is, the study team will collect information on medical problems which are also known as "treatment emergent adverse events" (TEAEs). And they will also collect levels of an electrolyte called potassium in the blood by taking blood samples, and measure blood pressure during the study. The secondary purpose of this study is to learn how well long-term use of finerenone can reduce the amount of protein in the participants' urine and benefit kidney function when taken with standard of care. To see how the treatment works, the study team will collect participants' urine samples to assess urinary albumin-to-creatinine ratio (UACR) and urinary protein-to-creatinine ratio (UPCR), which are important assessments for calculating the level of protein in the urine. Researchers will also collect blood samples to analyze serum creatinine and calculate estimated glomerular filtration rate (eGFR). A significant decline in eGFR indicates worsening kidney function. The study will include participants who had previously participated in FIONA study (NCT05196035). The participants will be aged from 1 year up to 18 years. The participants will be in the study for approximately 19 months. They will take study treatment for up to 18 months and will be follow up for 1 month. During this period, at least 12 visits are planned for patients who newly start finerenone, and at least 8 visits for patients who already received finerenone. In the visit, the study team will: * have their blood pressure, heart rate, temperature, height and weight measured * have blood and urine samples taken * have physical examinations * have their heart examined by an electrocardiogram and echocardiography (a sonogram of the heart) * answer questions about their medication and whether they have any adverse events, or have their parents or guardian's answer * answer questions about how they are feeling, or have their parents or guardian's answer * answer question about how they like the study medication, or have their parents or guardian's answer The doctors will keep track of any adverse events. An adverse event is any medical problem that a participant has during a study. Doctors keep track of all adverse events that happen in studies, even if they do not think the adverse events might be related to the study treatments. The doctors will check the participants' health about 30 days after the participants take their last treatment.

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