A Study to Learn More About How Safe Finerenone is, When it is Taken for a Longer Time With Standard Treatment, in Children and Young Adults With Heart Failure and Left Ventricular Systolic Dysfunction

Status: RECRUITING

Eligibility Criteria

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

- For participants rolling over from randomized controlled trial (RCT): Prior participation in the finerenone Phase 3 study FIORE (21466) and not permanently discontinued from the study intervention prior to the end of treatment (EoT) visit in FIORE.
- For newly enrolled infants <6 months of age: Left ventricular systolic dysfunction (LVSD) with left ventricular ejection fraction (LVEF) ≤ 50% at screening assessed by echocardiography.
- For newly enrolled infants <6 months of age: Elevated NT-pro BNP levels (> 500 mg/L) at screening.
- For newly enrolled infants <6 months of age: Heart failure (HF) etiologies include congenital heart defects (CHD) with biventricular physiology and systemic LV; idiopathic cardiomyopathy (CM); familial/inherited and/or genetic CM; history of myocarditis (diagnosis of an acute episode at least 3 months prior to treatment assignment); neuromuscular disorder; inborn error of metabolism; mitochondrial disorder; acquired (chemotherapy, iatrogenic, infection, rheumatic, or nutritional); ischemic (e.g., Kawasaki disease and postoperative HF); LV noncompaction.
- For newly enrolled infants <6 months of age: Receiving standard of care (SoC) treatment for heart failure according to local guidelines or investigator´s discretion (on a stable regimen for 30 days before baseline).
- Newly enrolled newborns and infants < 6 months of age must have a body weight of ≥3 kg at Visit 1.

Exclusion Criteria:

- For participants rolling over from randomized controlled trial (RCT): To roll-over to FIORELLO, all participants: Potassium (K+) >5.5 mmol/L. After unblinding:
    - For participants who received finerenone in FIORE: K+ >5.5 mmol/ L
    - For participants who received placebo in FIORE: K+ >5.0 mmol/L for children ≥2 years of age, and >5.3 mmol/L for children <2 years of age (if eGFR is <60 mL/min/1.73m² for participants <2 years of age, the serum potassium threshold of >5.0 mmol/L will be used for exclusion)
- For newly enrolled newborns and infants < 6 months of age: Potassium ≥ 5.3 mmol/l (if eGFR is <60 mL/min/1.73m², the serum potassium threshold of >5.0 mmol/L will be used for exclusion).
- For participants rolling over from RCT: Severe renal dysfunction with estimated glomerular filtration rate (eGFR) < 30 ml/min/1.73m² at FIORE EoT or Visit 1.
- For newly enrolled infants < 6 months of age: Severe renal dysfunction with eGFR < 30 ml/min/1.73m2 at screening or Visit 1.
- Treatment with a mineralocorticoid receptor antagonist, other than the study intervention, (e.g., spironolactone, eplerenone) within 30 days of Visit 1.
- Requirement of any intravenous (IV) vasoactive agents; mechanical ventilation; mechanical circulatory support; sustained or symptomatic arrhythmias not controlled by drug or device therapy within 30 days prior to study treatment.

Conditions & Interventions

Interventions:
DRUG: Finerenone (Kerendia, BAY94-8862)
Conditions:
Left Ventricular Systolic Dysfunction, Heart Failure (Pediatric)

More Information

Description:
Researchers are looking for a better way to treat children and young adults who have heart failure with left ventricular systolic dysfunction (LVSD). Heart failure with left ventricular systolic dysfunction (LVSD) is a condition where the left side of the heart is weak and struggles to pump blood effectively, leading to symptoms like shortness of breath, fatigue, and poor growth. The study treatment, finerenone (also called BAY94-8862), is under development to treat newborns, children, and young adults with heart failure and LVSD. It works by blocking a protein that contributes to inflammation, scarring, and thickening in the heart and blood vessels, which may help the heart pump more blood effectively. The main purpose of this study is to learn about how safe finerenone is and how well it works in the long-term treatment of heart failure and LVSD. To understand how safe the treatment is, the study team will gather information on the number of patients who experience medical problems after taking finerenone, also known as "treatment emergent adverse events" (TEAEs). Additionally, they will collect blood samples to measure levels of an electrolyte called potassium and monitor blood pressure. They will also assess kidneys function using the estimated glomerular filtration rate (eGFR). In this study, which is an extension of the earlier done FIORE study, finerenone will also be studied in newly enrolled newborns under 6 months with heart failure and LVSD and children and young adults from the FIORE study. The participants will be aged from newborns up to 18 years. All the participants will

continue to receive their standard treatment as routine care for heart failure, along with finerenone during the study. The participants will be in the study for around 10 to 11 months, depending on whether they rolled-over from the FIORE study or are newly enrolled newborns and infants \<6 months of age. They will take study treatment for up to 9 months. During this period, at least 6 visits are planned for participants. During these visits, the study team will: * have their blood pressure, heart rate, temperature, respiratory rate, height and weight measured * have blood samples taken * have physical examinations * have their heart examined by an electrocardiogram and echocardiography * answer questions about their medication and whether they have any adverse events, or have their parents or guardians' answer * for newborns and infants, evaluate the acceptability of the study drug formulation through parents or guardians' feedback. 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 a month after the participants take their last treatment.

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