# A Study to Learn More About How Well Finerenone Works, How Safe it is, and How it Moves Into, Through, and Out of the Body Compared to Placebo When Taken With Standard Treatment in Children With Heart Failure and Left Ventricular Systolic Dysfunction

Status: RECRUITING

## Eligibility Criteria

Sex: ALL
Age: 6 months to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Participants must be 6 months to <18 years old at the time when the informed consent/assent is signed.
- Left ventricular systolic dysfunction (LVSD) with left ventricular ejection fraction (LVEF) ≤ 50% at screening assessed by echocardiography.
- Elevated NT-pro BNP levels
    - >500 ng/l for children ≥ 6 months to < 2 years of age
    - >300 ng/l, for children ≥ 2 years to <18 years
- Heart failure etiologies including 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 was at least 3 months prior to randomization); neuromuscular disorder (eg, duchenne muscular dystrophy); inborn error of metabolism; mitochondrial disorder; acquired (chemotherapy, iatrogenic, infection, rheumatic, or nutritional); ischemic (eg, Kawasaki disease and postoperative heart failure [HF]); LV noncompaction.
- Receiving standard of care (SoC) treatment for heart failure according to local guidelines or investigator´s discretion and being on a stable regimen for 30 days prior to randomization.
- Study participants must have a body weight ≥ 4.0 kg at Visit 1.

Exclusion Criteria:

- Serum potassium:
    - > 5.0 mmol/L for children ≥ 2 years of age at either screening or randomization visit
    - > 5.3 mmol/L for children ≥ 6 months to < 2 years of age at either screening or randomization visit (if estimated glomerular filtration rate [eGFR] < 60 mL/min/1.73m², threshold of > 5.0 mmol/L will be used)
- Severe renal dysfunction with eGFR < 30 ml/min/1.73m² at screening or randomization visit.
- Systolic blood pressure (SBP) < 5th percentile for age, sex and height at screening or randomization.
- Sustained or symptomatic arrhythmias not controlled by drug or device therapy within 30 days prior to randomization.
- Treatment with a mineralocorticoid receptor antagonist (e.g., spironolactone, eplerenone) within 30 days of randomization.
- Requirement of any intravenous (IV) vasoactive agents, mechanical ventilation, mechanical circulatory support within 30 days prior to randomization.
- Recent surgical procedure or other intervention to correct or palliate CHD within 3 months prior to randomization or anticipated to undergo cardiac surgery during the 3 months after randomization.

## Conditions & Interventions

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

## More Information

Description:
Researchers are looking for a better way to treat children who have heart failure with left ventricular systolic dysfunction (LVSD). Heart failure is a serious condition where the heart is unable to pump enough blood to meet the body's needs. This can lead to symptoms like shortness of breath, fatigue, and poor growth in children. The study treatment, finerenone (also called BAY94-8862), works by blocking a protein involved in inflammation, scarring, and thickening of the heart and blood vessels. This may help the heart to pump blood more effectively. This is the first study to explore its use specifically for children with heart failure and LVSD. The main purpose of this study is to learn if finerenone works to help the heart compared to placebo in children with heart failure and LVSD. For this, the researchers will collect and analyze data on the levels of a protein called NT-proBNP in the blood, which indicates heart stress, and monitor the safety of the treatment. The study will include children with heart failure and LVSD aged from 6 months to less than 18 years. The study participants will be randomly assigned to one of two treatment groups. Based on their group, they will receive either finerenone or a placebo for a duration of 3 months. A placebo looks like a treatment but does not have any medicine in it. Throughout the study, all participants will continue to receive their standard heart failure treatments. At the start of this study, the doctors will

check each participant's medical history and current medications. If participants qualify for the treatment phase, they will undergo treatment for about 90 days. During this time, they will visit the study site at least 3 times. During these visits, the participants will: * have their blood pressure, heart rate, temperature, respiratory rate, height and weight measured * have their heart examined by electrocardiogram (ECG) and echocardiogram * have blood samples taken * have physical examinations * answer questions about their medication and whether they have any adverse events, or have their parents or guardians' answers 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. After the initial three-month study, eligible participants will have the option to join a nine-month open-label extension study where all will receive finerenone. Participants who choose not to enroll in the extension will have a follow-up visit 30 days after their last treatment.

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