A Study to Find Out How EMPAgliflozin is Tolerated and if it Helps Children and Adolescents With Chronic KIDNEY Disease (EMPA-KIDNEY® Kids)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 2 years to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Signed and dated written informed consent provided by the patient's parent(s) (or legal guardian) and patient's assent in accordance with international council for harmonisation good clinical practice (ICH-GCP) and local legislation prior to admission to the trial (informed assent will be sought according to the patient's age, level of maturity, competence, and capacity).
- Age 2 to 17 years at screening Visit 1.
- Chronic kidney disease (CKD) of any underlying aetiology defined by (as measured by central laboratory at screening Visit 1): estimated glomerular filtration rate (eGFR) (U25Crea) ≥20 to <90 mL/min/1.73 m2 with a urine-albumine-creatinine (UACR) ≥300 mg/g
- Participants must be on a stable dose of maximally tolerated standard of care (SoC) therapy for 30 days before screening visit 1 with no plans to change the dose throughout the duration of the placebo-controlled duration of the trial. SoC is anticipated to include a single Renin-angiotensin-aldosterone system (RAAS) inhibitor, such as angiotensin receptor blockers (ARB) or angiotensin converting enzyme inhibitors (ACEi) as appropriate and tolerated. Additional use of a mineralocorticoid receptor antagonist (MRA, including finerenone if available) is permitted if needed and the dose is stable for 30 days before screening Visit 1 and no planned dose changes for the placebo-controlled portion of the trial.
- Participants receiving daily immunosuppressive therapy for an underlying immunological cause of CKD must be on a stable dose for the duration specified for each drug prior to screening and must remain on a stable regimen throughout the placebo-controlled portion of the trial.
- Further inclusion criteria apply.

Exclusion Criteria:

- Confirmed type 1 or type 2 diabetes mellitus.
- History of ketoacidosis within 8 weeks prior to Visit 1 and up to randomisation.
- Chronic dialysis or functioning kidney transplant or scheduled for transplantation throughout the duration of the trial.
- Diagnosis of uncontrolled metabolic bone disease (at the Investigator's discretion).
- Body mass index (BMI) ≤10th percentile for children ≥4 years of age and ≤25th percentile for children <4 years of age according to Centers for Disease Control and Prevention (CDC) growth chart at screening Visit 1.
- Gastrointestinal disorders that might interfere with trial drug absorption according to investigator assessment.
- Presence of acute or active urinary tract infection (UTI) with signs or symptoms of an active UTI or therapeutic treatment for an active UTI within 14 days before screening Visit 1.
- Severe, uncontrolled hypertension (based on investigator's judgement).
- Further exclusion criteria apply.

Conditions & Interventions

Interventions:
DRUG: Empagliflozin, DRUG: Placebo
Conditions:
Chronic Kidney Disease

More Information

Description:
This study is open to children aged 2 to 17 with chronic kidney disease (CKD). The purpose of this study is to find out if a medicine called empagliflozin helps children and adolescents with CKD. Other goals of the study are to find out how empagliflozin is tolerated and handled by the body in children and adolescents with CKD. Participants are put into 2 groups randomly, which means by chance. One group takes empagliflozin and the other group takes placebo. Placebo looks like empagliflozin but does not contain any medicine. Participants are twice as likely to be in the empagliflozin group. Participants take empagliflozin or placebo as tablets once a day for 6 months. After 6 months, participants in both groups take empagliflozin as tablets once a day for 1 year. Participants are in the study for a little over a year and a half. During this time, they visit the study site about 15 times and get at least 5 phone or video calls from the site staff. At the visits, the doctors take blood and urine samples from the participants. The doctors also regularly check participants' health and take note of any unwanted effects.

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Phase: PHASE3
IRB Number:
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