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

Age: 2 years to 17 years old

This study is NOT accepting healthy

Healthy Volunteers: 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

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