

A randomised, double-blind, placebo-controlled trial with an open-label extension to assess the pharmacokinetics, safety, and efficacy of empagliflozin tablets in paediatric patients with chronic kidney disease (EMPA-KIDNEY® Kids)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Up to 18 years old

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 2 to 17 years old - Chronic kidney disease (CKD) of any type - on a stable dose of maximally tolerated standard therapy for at least 30 days - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- Type 1 or Type 2 diabetes mellitus - chronic dialysis or functioning kidney transplant or scheduled for transplantation - Body mass index (BMI) \leq 10th percentile for children \geq 4 years of age and \leq 25th percentile for children <4 years of age - gastrointestinal disorders that might interfere with drug absorption - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Conditions:

Kidney, Prostate & Urinary

Keywords:

Chronic kidney disease, CKD

More Information

Description: This study is for children aged 2 to 17 with chronic kidney disease (CKD). The purpose of this study is to find out if a study drug 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.

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Phase: PHASE3

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