Find CKD

Status ongoing: stop inclusion

S-nummer: S66745 Phase III study
Principal Investigator: prof. dr. Kathleen Claes

Title: A randomized, double-blind, placebo-controlled, parallel-group, multicenter phase 3 study to investigate the efficacy and safety of **FI**nerenone, in addition to standard of care, on the progression of kidney disease in patients with **N**on-**D**iabetic **C**hronic **K**idney **D**isease.

Purpose and rationale: To investigate the efficacy and safety of finerenone, i.e., 10 mg and 20 mg once daily, compared with placebo, on the progression of non-diabetic chronic kidney disease in patients, over minimum of 32-months of study intervention per participant, in addition to standard of care.

Primary endpoint: Mean rate of change as measured by the total slope of eGFR from baseline to month-32.

Medication/treatment: Finerenone (non-steroidal MRA) 10mg or 20mg (up-titration) once daily or matching placebo (randomization 1:1).

Duration of study: Approximately 33 to 50 months, consisting of 18 visits.

Key inclusion criteria:
- Male and female patients ≥ 18 years old
- Clinical diagnosis of chronic kidney disease:
    - eGFR ≥25 but <60 mL/min/1.73m² and UACR of ≥200 but <500 mg/g
    - Documentation of albuminuria/proteinuria
- Stable and max. tolerated labelled dose of an ACEI or ARB for at least 4 weeks prior to screening
- K+ ≤4.8 mmol/L

Key exclusion criteria:
- Diagnosis of Type 1 or 2 Diabetes mellitus, or HbA1c ≥ 6.5% (48 mmol/mol)
- ADPKD or ARPKD
- Lupus nephritis or ANCA-associated vasculitis or any other primary or secondary kidney disease requiring immunosuppressive therapy within 6 months prior to screening
- History of organ transplantation
- Dialysis within 6 months prior to screening
- Uncontrolled arterial hypertension (SBP ≥160 mmHg; DBP ≥100 mmHg)
- UACR >3500 mg/g