Continuity CKD

Ongoing: active inclusion

s-nummer: S66639 Phase IV study
Principal Investigator: prof. dr. Björn Meijers

Title: An Open-Label, Randomised, Phase 4 Study of Continuing Sodium Zirconium Cyclosilicate (SZC) after Discharge in Participants with Chronic Kidney Disease treated for Hyperkalaemia (CONTINUITY)

Purpose and rationale: This is an open-label, randomised study in participants with CKD treated for hyperkalaemia whilst in hospital. The study will compare SZC to standard of care (SoC) with the goal of determining: 1) If continued use of SZC maintains normokalaemia better than SoC after participant discharge from the hospital. 2) If continued use of SZC after discharge will reduce hyperkalaemia related healthcare resource utilisation compared to SoC.

Primary endpoint: Occurrence (yes/no) of normokalaemia ([K+] between 3.5 and 5.0 mmol/L, inclusive) at 180 days post-discharge.

Medication/treatment: Open-label Lokelma (SZC, K+ binder) or SoC medication as per local practice.

Duration of study: up to approximately 7 months, consisting of 8 visits of which 4 via a telephone call.

Key inclusion criteria:
- Male and females above the age of 18.
- Admitted to hospital
- Diagnosed CKD (any stage) or eGFR < 90 mL/min/1.73 m² at, or within 3 months of, study screening
- Local laboratory K+: Hyperkalaemic (K+ ≤ 6.5 mmol/L) or normokalaemic (K+ between ≥ 3.5 and ≤ 5.0 mmol/L)

Key exclusion criteria:
- Hospitalisation for an acute cardiovascular event within 12 weeks prior to screening
- With a life expectancy of less than 6 months
- QTcF > 550 msec
- Congenital long QT syndrome
- Ongoing treatment with SZC or patiromer before current ED visit/hospital admission
- Chronic dialysis or scheduled date for a kidney transplant