Varvara

Status ongoing: active inclusion

S-nummer: S67962 Phase 2 study
Principal Investigator: prof. dr. Dirk Kuypers

Title: A Phase 2, Multicenter, Randomized, Double-Blinded, Placebo-Controlled Study to Assess the Safety, Efficacy, and Tolerability of ARGX-117 in Improving Allograft Function in Recipients of a Deceased Donor Renal Allograft at Risk for Delayed Graft Function.

Purpose and rationale: ARGX-117 is a humanized recycling antibody that binds specifically to C2. Complement activation plays a significant role in the pathophysiology of IRI, a major contributor to poor early graft function and DGF. ARGX-117 is expected to reduce tissue inflammation by blocking complement activity. This population consists of recipients of a deceased donor renal allograft who are assessed as at risk for DGF.

Primary endpoint: eGFR at 24 weeks posttransplant

Medication/treatment: ARGX-117 (complement Inhibitor) IV 60 mg/kg or placebo on day 1 and day 8. All participants will also receive medicines that control their immune system that are required to prevent kidney rejection. Some medicines will also be required to lower the risk of serious infections.

Duration of study: Approximately 64 weeks, consisting of 16 up to 20 visits.

Key inclusion criteria:
- Cold ischemia time (CIT) ≥12 hours
- Donor aged ≥40 and <70 years AND/OR donor terminal serum creatinine >1.5 mg/dL
- Male or female recipient aged between 18 and 70 years
- Diagnosed with ESRD and have been stable on chronic dialysis for at least 3 months
- Recipients of *de novo* or second-time, single kidney transplant from a deceased donor (DCD or DBD)
- ABO compatible with donor allograft, except for type A2 donor to type B recipient kidneys
- Negative cross match

Key exclusion criteria:
- Any history of participant anti-HLA DSA to the current donor
- Donor kidney that is continuously machine perfused from the time of organ procurement to the time of transplant
- Donor kidney from an HIV positive donor
- Any known history of complement deficiency
- Received any solid organ, bone marrow, or hematopoietic stem cell transplant (exception: kidney)
- AST/ALT ≥2xULN, total bilirubin ≥1.5xULN, absolute neutrophil count <1000 cells/µL, Hb <8.0g/dL, WBC <3000 cells/µL, platelet count <100 000/µL
- Positive serology for HIV or active infection (HBV, HCV)
- Recipient history of tuberculosis infection