Optimize

Status ongoing: stop inclusion

S-nummer: S63008 Academic study
Principal Investigator: prof. dr. Dirk Kuypers

Title: **OP**en label multicenter randomized **T**rial comparing standard **IM**munosuppression with tacrolimus and mycophenolate mofetil with a low exposure tacrolimus regimen **I**n combination with everolimus in de novo renal transplantation in **E**lderly patients.

Purpose and rationale: To test the hypothesis that an age-adapted immunosuppressive regimen targeted at reduced immunosuppression with low calcineurin inhibitor (tacrolimus) exposure in combination with everolimus will result in improved outcome in elderly (>65 yrs) recipients of A: Kidneys from older deceased donors (>64 years) and B: Kidneys from living donors (all ages) and younger deceased donors (<65 years).

Primary endpoint: The primary endpoint will be "successful transplantation" which is defined as survival with a functioning allograft with a minimum estimated GFR of 30 ml/min per 1.73 m2 in stratum A and 45 ml/min per 1.73 m2 in stratum B, after 2 years.

Medication/treatment: standard immunosuppression with Tacrolimus once-daily and Mycophenolate Mofetil versus a low exposure Tacrolimus once-daily regimen in combination with Everolimus.

Duration of study: 24 months, existing of 3 visits

Key inclusion criteria:
- Male or female subject ≥65 years old
- Stratum A: Recipient of a primary (or secondary, if first graft is not lost due to immunological reasons) renal transplant from a deceased donor aged 65 years or older
- Stratum B: Recipient of a primary (or secondary, if first graft is not lost due to immunological reasons) renal transplant from a deceased donor aged below 65 years or a living donor of any age

Key exclusion criteria:
- Multi-organ transplant recipient
- Recipient of blood group ABO incompatible allograft or CDC cross-match positive transplant
- HLA-identical related living donor
- Subject who is HIV positive
- Subject with severe systemic infections
- Subject with WBC count ≤ 2,000/mm³ or with platelet count ≤ 50,000/mm³