MIPD (Model-Informed Precision Dosing) of tacrolimus

Status ongoing: active inclusion

S-nummer: S63463 Academic study
Principal Investigator: prof. dr. Dirk Kuypers

Title: Integrated Model-based Medication Dosing Assist App(lication) in Klinisch Werk Station (KWS). Proof-of-Concept Validation Study: Tacrolimus in Kidney Transplantation.

Purpose and rationale: Clinical-scientific validation study on the use of a computer-assisted application (App) that supports the physician in determining the correct dosage of tacrolimus, which is essential to prevent rejection after kidney transplantation.

Primary endpoint: The time to reach 3 in-target samples in the 8 days following transplant.

Medical device: determination of the dosage of Tacrolimus via an integrated Application or via standard clinical practice.

Duration of study: 14 days or until day of discharge after transplantation if occurring earlier than 14 days.

Key inclusion criteria:
- Male and female patients from the age of 18 years
- Patients receiving a single deceased or living donor kidney transplantation or re-transplantation
- Patients treated with an oral tacrolimus formulation in combination with mycophenolic acid aiming at standard target tacrolimus concentration ranges (12-15 µg/L)

Key exclusion criteria:
- Patients receiving a combined kidney transplantation