

Assessment of Biomarker-Guided CNI Substitution In Kidney Transplantation

NCT05917522

Status	RECRUITING
Phase	Phase 2
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
Enrollment	800 participants

Key Eligibility Criteria

Inclusion (25)

- Observational Study:
 - Subject must be able to understand and provide informed consent
 - Received (within 14 days) or candidate for an ABO-compatible kidney transplant, including A2 to B
 - Panel Reactive Antibody $\leq 60\%$ as determined by local site
 - Virtual cross-match negative as determined by local site or Donor Specific Antibody (DSA) negative by central lab within 14 days post-transplant
- ... and 20 more (see full listing online)

Exclusion (31)

- Observational Study:
 - Inability or unwillingness of a participant to give written informed consent or comply with study protocol including a mandated 6-mo kidney transplant biopsy
 - Non-Kidney Transplant (KTx) (pre-existing or concurrent)
 - Current use of immunomodulatory agents (including but not limited to: Rituximab, anti-Tumor necrosis factor(TNF) Monoclonal antibodies (mAb), or Belatacept, abatacept, Janus kinase inhibitors)
 - Transplant in which the kidney donor is the recipient's Identical twin
- ... and 26 more (see full listing online)

Locations (15 total)

University of Alabama School of Medicine: Transplantation, Birmingham, Alabama, United States
Cedars Sinai Medical Center: Transplantation, Los Angeles, California, United States
Ronald Reagan UCLA Medical Center: Transplantation, Los Angeles, California, United States
... and 12 more locations

<https://clinicaltrials.gov/study/NCT05917522>

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