

Early Trial of Allogeneic Hematopoietic Stem Cell Transplantation for Patients Who Will Receive a Kidney Transplant From the Same Donor

NCT05508009

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Alice Bertaina
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (8)

- Anticipated need for kidney transplant due to:
 - a. Underlying genetic/immunologic disease the following conditions i. SIOD ii. FSGS iii. Cystinosis iv. SLE v. Membranoproliferative glomerulonephritis vi. Renal vasculitis characterized by positivity of the presence of ANCA vii. Other genetic diseases leading to kidney disease requiring KT Or b. Patients who have rejected a previous KT regardless of the underlying disease
 - Chronic kidney disease (CKD) stage 3 or greater
 - Steroids \leq 0.5 mg/Kg/day
 - The donor and recipient must be identical, as determined by high resolution typing, at least one allele of each of the following genetic loci: HLA-A, HLA-B, HLA-Cw, HLA-DQB1 and HLA-DRB1
- ... and 3 more (see full listing online)

Exclusion (8)

- Pregnant or lactating females.
 - Greater than Grade II aGvHD or severe, unmanaged extensive cGvHD due to a previous allograft at the time of inclusion
 - Dysfunction of liver (ALT/AST $>$ 10 times upper normal value, or direct bilirubin $>$ 3 times upper normal value), unmanageable dysfunction of renal function while undergoing dialysis
 - Severe cardiovascular disease at the time of evaluation unresponsive to nutritional and dialytic support (left ventricular ejection fraction $<$ 40%), or clinical or echocardiographic evidence of severe diastolic dysfunction
 - Current active infectious disease. Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial. For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated. Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. Patients with HCV infection who are currently on treatment are eligible if they have an undetectable HCV viral load.
- ... and 3 more (see full listing online)

Locations (1 total)

Lucile Packard Children's Hospital, Palo Alto, California, United States

<https://clinicaltrials.gov/study/NCT05508009>

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