

Kidney Transplant Preemptive Therapy or Prophylaxis for CMV Prevention in D+R Recipients

NCT06798909

Status	RECRUITING
Phase	Phase 3
Sponsor	University of California, San Francisco
Enrollment	360 participants

Key Eligibility Criteria

Inclusion (7)

- Subject or legally authorized representative has provided written informed consent.
- Age ≥ 18 years of age at the time of informed consent.
- Negative for IgG antibody to CMV as assessed in a CLIA-certified laboratory between 28 days prior to transplant and up to 7 days post-transplant but prior to randomization.
- Received a kidney transplant from a CMV seropositive (IgG positive) donor in the past 7 days prior to enrollment
- Individuals of reproductive (childbearing) potential must have a negative pregnancy test (serum or urine) collected prior to randomization (SOC results within 7 days prior to transplant may be used), and must also agree to use a medically approved method of contraception. Acceptable methods include: barrier method, intrauterine device (hormonal or non-hormonal), oral hormonal contraceptives, abstinence from the time of enrollment through until discontinuation of ganciclovir or valganciclovir in either arm during the intervention period.

... and 2 more (see full listing online)

Exclusion (15)

- In the opinion of the investigator, participants who are unable or unwilling to undergo preemptive therapy protocol (weekly CMV PCR, etc.)
- Patients who are breastfeeding or planning to breastfeed within 6 months post-transplant
- Allergy to valganciclovir/ganciclovir or Letermovir
- Receipt of immunoglobulin or CMV-specific immunoglobulin within the last 3 months (this includes COVID convalescent plasma)
- Currently enrolled or anticipated enrollment in another interventional study that, in the opinion of scientific leadership team, could affect evaluation of the primary safety and/or efficacy outcomes.

... and 10 more (see full listing online)

Locations (5 total)

University of California, San Francisco School of Medicine, San Francisco, California, United States

University of Miami Miller School of Medicine, Miami, Florida, United States

Emory University School of Medicine, Atlanta, Georgia, United States

... and 2 more locations

<https://clinicaltrials.gov/study/NCT06798909>

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