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

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Subject or legally authorized representative has provided written informed consent. 2. Age ≥ 18 years of age at the time of informed consent. 3. Negative for antibody to CMV as assessed in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory between 28 days prior to transplant and 7 days post-transplant, but prior to enrollment, and no history of positive CMV serology Immunoglobulin G (IgG) antibody 4. Received a first kidney transplant from a CMV seropositive donor in the past 7 days prior to enrollment 5. Individuals of reproductive (childbearing) potential must have a negative pregnancy test (serum or urine) collected prior to randomization (standard of care (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 1 month after discontinuation of either PET or AP. NOTE: Individuals of reproductive potential are defined as individuals who have reached menarche and who have not been post-menopausal for at least 12 consecutive months with follicle stimulating hormone (FSH) ≥40 IU/mL or 24 consecutive months if an FSH is not available, i.e., who have had menses within the preceding 24 months, and have not undergone a sterilization procedure (e.g., hysterectomy, bilateral oophorectomy, or salpingectomy). 6. If male, and not surgically sterile, must agree to practice barrier method of contraception or abstinence from the time of enrollment through 1 month after discontinuation of either PET or AP.

Exclusion Criteria:

1. In the opinion of the investigator, participants who are unable or unwilling to undergo preemptive therapy protocol (weekly CMV PCR, etc.) 2. Patients who are breastfeeding or planning to breastfeed within 6 months post-transplant 3. Allergy to valganciclovir/ganciclovir or Letermovir 4. Receipt of immunoglobulin or CMV-specific immunoglobulin within the last 3 months (this includes COVID convalescent plasma) 5. Currently enrolled in another interventional study that, in the investigator's opinion, could affect evaluation of the safety and/or efficacy outcomes 6. Most recent platelet count post-transplant \<25,000/uL 7. Most recent ANC performed post-transplant \<1000/uL 8. Multi-organ transplant or have undergone prior organ transplant 9. Baseline immunodeficiency prior to transplant: 1. Known or suspected human immunodeficiency virus (HIV) infection 2. Congenital or acquired immunodeficiency 10. Unacceptable immunosuppression 1. Receipt of desensitization therapy prior to kidney transplant, or 2. Receipt of a blood type A, B, or O-incompatible kidney transplant, or 3. Receipt or planned receipt of any of the following: belatacept, alemtuzumab, or rituximab

Conditions & Interventions

Interventions:
DRUG: Valganciclovir (Pre-emptive CMV Therapy), DRUG: Valganciclovir CMV Prophylaxis
Conditions:
Cytomegalovirus (CMV), Kidney Transplant, Complications, Kidney Diseases

More Information

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