De-novo Initiation of Letermovir vs Valganciclovir for Cytomegalovirus Prophylaxis in AA Kidney Transplant Recipients

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Historical Control group: Inclusion Criteria 1. Kidney transplant recipients 2. Male or female age ≥ 18 years old 3. African American race 4. CMV high risk (D+/R-) 5. received valganciclovir for CMV prophylaxis Historical Control group: Exclusion 1. Re-transplantation 2. Panel of reactive antibody ≥80% at the time of transplant 3. Positive cytotoxic cross match at the time of transplant Experimental Group Inclusion Criteria 1. Kidney transplant recipients 2. Male or female age ≥ 18 years old 3. African American race 4. CMV high risk (D+/R-) 5. Ability to provide informed consent before any trial related activities Exclusion Criteria 1. Re-transplantation 2. Panel of reactive antibody ≥80% at the time of transplant 3. Positive cytotoxic cross match at the time of transplant 4. Pregnancy and Breastfeeding 5. Prisoners 6. Patients with hypersensitivity to acyclovir, valacyclovir or any of its components 7. Patients with hypersensitivity to Letermovir or any of its components 8. If Patients are taking any of these medications: pimozide, ergot alkaloids (ergotamine, dihydroergotamine), or pitavastatin/simvastatin co-administered with cyclosporine, we will work with the prescribing physician to find an appropriate replacement therapy which will not interfere with any study-related interventions. Otherwise, participants will be excluded from the study.

Conditions & Interventions

Interventions:

DRUG: Letermovir 480 mg once daily, OTHER: Historical/Control

Conditions:

Kidney Transplant, Complications, CMV

More Information

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Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06001320