

# A Study Comparing Siplizumab With Rabbit Anti-Thymocyte Globulin to Help the Body Accept a Kidney Transplant

**Status:** RECRUITING

## Eligibility Criteria

**Age:** 18 years to 70 years old

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

### Inclusion Criteria:

\* Recipients of a renal allograft from a non-HLA identical living or deceased donor. \* Recipients of a kidney with a cold ischemia time  $\leq$  30 hours; hypothermic machine perfusion within the same timeframe is acceptable. \* Women of childbearing potential, defined as all women physiologically capable of becoming pregnant, must agree to use highly effective methods of contraception.

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### Exclusion Criteria:

\* Transplant recipients seronegative for EBV. \* Transplant recipients receiving a kidney from a non-heart beating donor (ie, DCD) whose organ is retrieved from an uncontrolled DCD or whose donor age  $\geq$  55 years of age. \* Multi-organ transplant recipients (eg, kidney-pancreas, organ other than kidney), dual-kidney transplant recipients, recipients with more than one prior kidney transplant, or hematopoietic stem cell transplantation recipients. \* Presence of current or historical DSA via single-antigen bead assay or local SoC. The MFI cut-off value used to determine the presence of DSA will be defined as per the institutional SoC. Results within 3 months prior to transplant are acceptable. \* Crossmatch positive (isolated positive B cell crossmatches are not an exclusion criterion). \* ABO-incompatible recipient. \* Administration of complement inhibitor therapy within 6 months prior to the transplant, or likely to require treatment with complement inhibitor therapy during the study. \* Participants receiving immunosuppressive therapies prior to transplant for pre-existing conditions must be candidates for the protocol-defined regimen. \* History of malignancy of any organ system, except for localized excised non-melanomatous skin lesions or carcinoma in situ of the cervix. \* Seropositive for human immunodeficiency virus or hepatitis B surface antigen. Participants who are seropositive for hepatitis C virus (HCV) are excluded without proof of sustained viral response after anti-HCV treatment. \* Recipient of a kidney from a donor who tests positive for human immunodeficiency virus or hepatitis B surface antigen/hepatitis B core protein. \* History of hypersensitivity to any of the study drugs or to drugs of similar chemical classes (eg, siplizumab, rATG, TAC, MPA derivatives, CS). \* Evidence of active tuberculosis (TB) infection (participants with a history of latent TB may become eligible after treatment with anti-TB therapy according to national guidelines). \* Participants with severe systemic infection(s), at the time of screening or within 2 weeks prior to randomization

## Conditions & Interventions

### Interventions:

DRUG: Siplizumab, DRUG: Rabbit anti-thymocyte globulin

### Conditions:

Renal Transplant Failure and Rejection

## More Information

**Contact(s):** ctrrecruit@vcu.edu

**Principal Investigator:**

**IRB**

**Number:**

**System ID:** NCT07508787

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