# Advancing Transplantation Outcomes in Children

Status: RECRUITING

## Eligibility Criteria

Sex: ALL
Age: 13 years to 20 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Participant and/or parent/guardian must be able to understand and provide informed consent
2. Male or female, 13-20 years of age at time of enrollment
3. Candidate for primary renal allograft from a living or deceased donor
4. EBV IgG seropositive, defined as evidence of acquired immunity shown by the presence of IgG antibodies to viral capsid antigen (VCA) and EBV nuclear antigen (EBNA)
5. EBV VCA IgM seronegative OR EBV VCA IgM seropositive on two occasions at least 3 months apart and an undetectable EBV PCR result within 1 month prior to enrollment
6. If a female participant of childbearing potential, a negative pregnancy test prior to conducting any study procedures
7. If participant has reproductive potential, agrees to use Food and Drug Administration (FDA) approved methods of birth control for the duration of the study
8. Negative test result for latent tuberculosis infection by tuberculosis skin test (purified protein derivative [PPD]) or Tuberculosis (TB) blood test (interferon gamma release assay [IGRA] i.e., QuantiFERON, T- SPOT.TB) within 12 months
9. In the absence of contraindication, vaccinations must be up to date per the Centers for Disease Control and Prevention (CDC) Guidelines and Division of Allergy, Immunology, and Transplantation (DAIT) Guidance for Patients in Transplant Trials

Enrollment criteria for donor source and age will be expanded using a stepwise approach determined by safety monitoring. Expansion criteria will include recipients down to age 6 and living donors. Safety data from each step will be reviewed by the study team, DSMB and FDA. If no safety concerns are identified, inclusion criteria will be expanded.

Exclusion Criteria:

1. Inability or unwillingness to comply with study protocol
2. Active infection requiring treatment, or viremia
3. History of malignancy
4. Receipt of any licensed or investigational live attenuated vaccine(s) within 4 weeks of enrollment
5. Prior history of organ transplantation
6. Listed for multi-organ transplant (e.g. heart- kidney, liver-kidney, multivisceral- kidney, lung- kidney)
7. Active systemic autoimmune disease at time of enrollment
8. Idiopathic Focal Segmental Glomerulosclerosis (FSGS), Membranoproliferative Glomerulonephritis (MPGN), C3 glomerulopathy, or atypical Hemolytic Uremic Syndrome (HUS) suspected at risk for recurrence
9. Use of immunosuppressants, biologics (including IVIG), chronic corticosteroids or investigational drug(s) within 8 weeks of enrollment
10. Known bleeding disorder
11. Sustained platelet count < 75,000 cells/microliters within 3 months of enrollment
12. History of inherited hypercoagulability requiring therapy more than aspirin
13. Panel Reactive Antibody (cPRA) greater than 80 percent
14. Clinically significant unrepaired congenital heart disease causing hemodynamic compromise
15. Uncontrolled diagnosed psychiatric disorder or self-reported drug or alcohol abuse that, in the opinion of the investigator, would interfere with the participant's ability to comply with study requirements
16. Past or current medical problems or findings from physical examination or laboratory testing that are not listed above, which, in the opinion of the investigator, may pose additional risks from participation in the study, may interfere with the participant's ability to comply with study requirements or that may impact the quality or interpretation of the data obtained from the study

Randomization Inclusion Criteria:

Individuals who meet all of the following criteria are eligible for randomization.

1. If EBV serology to meet enrollment criteria was performed within 8 weeks of receiving IVIG, EBV VCA IgG and EBV EBNA IgG seropositivity, confirmed between enrollment and time of transplant

Randomization Exclusion Criteria:

Individuals who meet any of these criteria are not eligible for randomization.

1. Sustained WBC <1500 or >20,000 per microliter within 3 months of randomization
2. Sustained liver function tests (AST and/or ALT) > 2x normal within 3 months of randomization
3. Active systemic autoimmune disease at time of transplant
4. Known bleeding disorder
5. Sustained platelet count < 75,000 cells/microliters within 3 months of enrollment
6. Current (within 45 days) or historical anti-HLA antibody to the donor prior to randomization

6. Current (within 45 days) of historical anti-HLA antibody to the donor prior to randomization
7. Recent recipient of any licensed or investigational live attenuated vaccine(s) within 4 weeks of randomization
8. Panel Reactive Antibody (cPRA) greater than 80 percent at any point in time
9. If a female participant of childbearing potential, a positive pregnancy test within 48 hours of randomization (all female participants of childbearing potential must complete a pregnancy test within 48 hours of randomization)
10. Treatment with immunosuppressants within 8 weeks of randomization, except in the case of planned transplant standard of care
11. Treatment with biologics (including IVIG) within 8 weeks of randomization

## Conditions & Interventions

Interventions:
DRUG: Sirolimus, BIOLOGICAL: Belatacept, DRUG: Mycophenolate Mofetil, DRUG: Tacrolimus (Group1), DRUG: Anti-Thymocyte Globulin (ATG), DRUG: Tacrolimus (Group 2)
Conditions:
Kidney Transplant
Keywords:
kidney transplant, belatacept, sirolimus

## More Information

Description:
This is a pediatric kidney transplant study comparing the safety and efficacy of an immunosuppressive regimen of belatacept and sirolimus to tacrolimus and Mycophenolate Mofetil (MMF). Two hundred participants will be randomized (1:1) to one of two groups within 24 hours following the transplant procedure. The duration of the study from time of transplant to the primary endpoint is 12-24 months.

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