

A Study to Learn About the Effects of Felzartamab Infusions in Adults With Kidney Transplants Who Have Late Isolated Microvascular Inflammation

NCT07219043

Status	RECRUITING
Phase	Phase 2
Sponsor	Biogen
Enrollment	81 participants

Key Eligibility Criteria

Inclusion (7)

- MVI (MVI e2), donor specific antibody (DSA)-negative that is either complement activation (C4d) negative or C4d positive (biopsy-confirmed) without T cell-mediated rejection (TCMR) per central reading, as defined by the Banff 2022 criteria.
- Biopsy must be within 3 months (preferably within 1 month) prior to randomization and meet adequate criteria (option a preferred over option b):
- Adequate: 10 or more non-sclerotic/evaluable glomeruli and two muscular arteries
- Minimally Adequate: at least 7 non-sclerotic/evaluable glomeruli and one muscular artery
- For participants who received any prior treatment for antibody-mediated rejection (AMR), MVI, or TCMR as outlined in Exclusion Criterion 5, the biopsy must be performed at least 6 weeks after completing (or stopping) prior treatment.

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

Exclusion (11)

- Transplant: Blood type (ABO)-incompatible transplant.
- History of multiple organ transplants including en bloc and dual kidney transplants.
- Presence of HLA donor-specific antibodies.
- Acute, rapid decline in renal function, defined as a participant likely to require renal replacement therapy within the next 30 days as determined by the Investigator.
- Prior AMR or TCMR treatment (with the exception of corticosteroids) within 3 months prior to randomization is excluded as listed below. Participants who received any of these treatments between 3 and 6 months prior to randomization must have both a renal biopsy (IC3) and DSA testing at least 6 weeks after completing (or stopping) treatment in order to confirm continuing MVIe2 and DSA negative status and to determine eligibility:

... and 6 more (see full listing online)

Locations (14 total)

Keck Hospital of University of Southern California (USC), Los Angeles, California, United States
Providence St. Joseph Hospital Orange, Orange, California, United States
Sutter Health - California Pacific Medical Center, San Francisco, California, United States

... and 11 more locations