

A Study to Learn More About the Effects and Safety of Felzartamab Infusions in Adults With Kidney Transplants Who Have Antibody-Mediated Rejection (AMR)

NCT06685757

Status	RECRUITING
Phase	Phase 3
Sponsor	Biogen
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (3)

- Active or chronic active AMR (biopsy-confirmed) without TCMR per central reading, as defined by the Banff 2022 criteria.
- Kidney transplant at least 6 months prior to Screening visit (recipients of either living or deceased donors).
- Donor-specific antibody (DSA): Human leukocyte antigen (HLA) Class I and/or II antigen-specific DSA-positive (preformed and/or de novo DSA) as determined by the local laboratory's definition of positivity using singleantigen bead-based assays within 3 months prior to randomization.

Exclusion (10)

- Transplant: Blood type (ABO)-incompatible transplant.
- History of multiple organ transplants including en bloc and dual kidney transplants.
- Acute, rapid decline in renal function, defined as a participant likely to require renal replacement therapy within the subsequent 30 days as determined by the Investigator.
- Treatment: Prior AMR/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 AMR and to determine eligibility:
- Intravenous or subcutaneous immunoglobulin (IVIg or subcutaneous immunoglobulin \[SCIg\]) or PLEX.

... and 5 more (see full listing online)

Locations (59 total)

University of Southern California, Los Angeles, California, United States
Cedars-Sinai Medical Center, Los Angeles, California, United States
UCLA, Los Angeles, California, United States
... and 56 more locations

<https://clinicaltrials.gov/study/NCT06685757>

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