

Open-Label, Phase II Trial of Isatuximab for Patients With Refractory Immune Cytopenias After Allogeneic Hematopoietic Cell Transplantation

NCT05873205

Status	RECRUITING
Phase	Phase 2
Sponsor	Memorial Sloan Kettering Cancer Center
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (24)

- Age ≥ 18 years (There are no dosing/AE data for isatuximab in children).
- Disease for which patient underwent an allo-HCT is in documented remission.
- Patients must have previously had documented primary neutrophil and platelet engraftment, defined as:
 - Neutrophil engraftment: the first of 3 successive days with an absolute neutrophil count of $\geq 500/\mu\text{L}$ after post-transplantation nadir.
 - Platelet engraftment: the first of 3 consecutive days with a platelet count of 20,000/ μL or higher in the absence of platelet transfusion for 7 consecutive days.

... and 19 more (see full listing online)

Exclusion (15)

- Presence of relapse/progression of malignant disease for which the patient underwent allo-HCT
- Patients with anemia and/or thrombocytopenia related to transplant-associated thrombotic microangiopathy.
- Patients with active GVHD requiring therapy may be eligible if the GVHD is responsive to treatment ($<$ grade 4 in severity), and after agreement between the sponsor and principal investigator.
- Organ insufficiency based on above criteria.
- Pregnancy or unwillingness to agree to birth control as noted above.

... and 10 more (see full listing online)

Locations (7 total)

Memorial Sloan Kettering Basking Ridge (Limited Protocol Activities), Basking Ridge, New Jersey, United States
Memorial Sloan Kettering Monmouth (Limited Protocol Activities), Middletown, New Jersey, United States
Memorial Sloan Kettering Bergen (Limited protocol activities), Montvale, New Jersey, United States

... and 4 more locations