

Second or Greater Allogeneic Hematopoietic Stem Cell Transplant Using Reduced Intensity Conditioning (RIC)

NCT01666080

Status	RECRUITING
Phase	Not Applicable
Sponsor	Masonic Cancer Center, University of Minnesota
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (9)

- Diagnosis of any disease for which a second or greater hematopoietic stem cell transplant is needed due to insufficient donor chimerism following hematopoietic recovery after previous HSCT. Determination of "insufficiency of donor chimerism" will be made by the treating transplant physician. Occasionally donor derived engraftment may be present, but sustained aplasia or failed recovery of sufficient hematopoiesis requires administration of a second graft. This intervention may be used for both situations.
- Donor Availability: Patients considered for transplantation must have a sufficient graft as based on current criteria of the University of Minnesota Blood and Marrow Transplantation Program
- Transplantation using sufficiently matched related donors (such as matched siblings) or unrelated donors will be considered. Both granulocyte-colony stimulating factor (GCSF) stimulated peripheral blood grafts and bone marrow grafts will be considered, although bone marrow will be the priority.
- Cord blood grafts, both related and unrelated, are also eligible. As this protocol will use a reduced intensity regimen, this protocol will use the current recommendations of the University of Minnesota for choosing cord blood grafts. If a single cord blood unit cell dose is insufficient, double cord transplantation should be considered if sufficiently matched cord blood units are available. The priority of choosing cord blood donors is based on the current institutional recommendations.
- Exclusion of Metabolic Disorder or other Inherited Disorder Carrier Status from related donor and unrelated cord blood grafts as appropriate for primary disease.

... and 4 more (see full listing online)

Exclusion (5)

- Previous irradiation that precludes the safe administration of an additional dose of 200 cGy of total body irradiation (TBI). Radiation Oncology will evaluate all patients who have had previous radiation therapy or TBI for approval to receive an additional 200 cGy of TBI
- Pregnant or breastfeeding
- Active, uncontrolled infection - infection that is stable or improving after 1 week of appropriate therapy (4 weeks for presumed or documented fungal infections) will be permitted
- HIV positive
- While it would be advantageous to begin therapy on this second transplant regimen \geq 6 months following a prior myeloablative regimen or \geq 2 months after a reduced intensity regimen, it is recognized that there are circumstances where this may not be practical.

Locations (1 total)

Masonic Cancer Center, University of Minnesota, Minneapolis, Minnesota, United States

<https://clinicaltrials.gov/study/NCT01666080>

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