Precision Alemtuzumab Dosing for Allogeneic Hematopoietic Cell Transplantation

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age:
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Patients who are undergoing allogeneic HCT at CCHMC with an alemtuzumab-containing preparative regimen for treatment of a non-malignant disease are eligible.
- For the first 7 patients, patients must have a 10/10 HLA matched related or unrelated stem cell donor, or be receiving a CD34+ selected stem cell product. After the first 7 patients, any donor match may be allowed after data review by the BMT clinicians and the PI.

Exclusion Criteria:

- Patients with a history of anaphylaxis to alemtuzumab.
- Patients who have previously received alemtuzumab and have not cleared alemtuzumab prior to the start of the preparative regimen.
- Life expectancy less than 4 weeks.
- Patients receiving dialysis or plasmapheresis at the time of the start of the conditioning regimen.
- Failure to sign informed consent and/or assent, or inability to undergo informed consent process.
- It is not medically advisable to obtain the specimens necessary for this study.
- Not able to tolerate subcutaneous dosing (patients with severe skin conditions).
- Patients with cancer.
- Patients whose clinical condition suggest there may be inability to successfully perform the PK modeling such as, but not limited to, active flaring of hemophagocytic lymphohistiocytosis in which excessive lymphoproliferation may significantly alter the target-mediated clearance of alemtuzumab and prevent observation of non-target mediated clearance which is needed for robust modeling.
- Patients whose pre-alemtuzumab level reveals an interfering substance which prevents accurate measurement of alemtuzumab.

Conditions & Interventions

Interventions:
DRUG: Alemtuzumab
Conditions:
Allogeneic Hematopoietic Cell Transplantation

More Information

Description:
Alemtuzumab is an antibody that reduces the strength of the immune system that is given in preparation for allogeneic hematopoietic cell transplant (HCT). In this research study the investigators want to find out if they can adjust the dose of alemtuzumab used as part of allogeneic HCT to target the level of Day 0 (the planned day of graft infusion) to an optimal therapeutic window of 0.15-0.9 ug/mL.

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