

# A Study of Treatment of Inflammation Before Stem Cell Transplant in People With a Primary Immune Regulatory Disorder (PIRD) and/or an Autoinflammatory Condition

NCT05787574

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2
<b>Sponsor</b>	Memorial Sloan Kettering Cancer Center
<b>Enrollment</b>	39 participants

## Key Eligibility Criteria

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### Inclusion (23)

- Patients receiving first allo-HCT for the following immunologic conditions:
  - Primary Immune Regulatory Disorder with or without a genetic lesion as defined by the Primary Immune Deficiency Treatment Consortium (PIDTC)
  - Patients with autoinflammatory disorders evidenced by cytokine or inflammation assays with at least 1.5x ULN of measured cytokines and/or an elevated ferritin or ESR  $\geq$  2 ULN
  - For inclusion on the emapalumab group, the lesion must be isolated to the IFN $\gamma$  pathway (or mediators thereof) with an elevated CXCL9  $\geq$  1.5 ULN OR sIL2R  $\geq$  1.5 ULN (or already controlled on immune modulation, provided that CXCL9 or sIL2R levels were elevated prior to initiation of immune modulation). Inclusion on the Fludarabine/dexamethasone group requires inflammation (as defined above) other than an isolated IFN $\gamma$  pathway
  - Able to tolerate cytoreduction (based on adequate organ function as described below)
- ... and 18 more (see full listing online)

### Exclusion (6)

- Uncontrolled infection at the time of enrollment.
  - Patients who have undergone previous allo-HCT.
  - Patient seropositivity for HIV I/II and/or HTLV I/II.
  - Females who are pregnant or breastfeeding.
  - Patients unwilling to use contraception during the study period.
- ... and 1 more (see full listing online)

## Locations (12 total)

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University of California, San Francisco (Data collection only), San Francisco, California, United States  
Children's Healthcare of Atlanta (Data Collection Only), Atlanta, Georgia, United States  
Memorial Sloan Kettering Basking Ridge (Limited Protocol Activities), Basking Ridge, New Jersey, United States  
... and 9 more locations