

Haploidentical HCT for Severe Aplastic Anemia

NCT04558736

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| Status | RECRUITING |
| Phase | Phase 2 |
| Sponsor | St. Jude Children's Research Hospital |
| Enrollment | 21 participants |

Key Eligibility Criteria

Inclusion (26)

- Age less than or equal to 21 years at time of enrollment.
- Confirmed diagnosis of SAA or a single lineage cytopenia
- (a) SAA or single lineage cytopenia will be defined as follows:
 - i. Bone marrow cellularity \leq 25% or hypocellular marrow for age, AND
 - ii. One or more of the following (in peripheral blood): (i) Neutrophils \leq $0.5 \times 10^9/L$ (ii) Platelets \leq $20 \times 10^9/L$, or platelet transfusion dependence (iii) Hemoglobin \leq 8g/dL, or red blood cell transfusion dependence

... and 21 more (see full listing online)

Exclusion (12)

- Diagnosis of Fanconi anemia. Fanconi anemia must be excluded by diepoxybutane (DEB) or equivalent testing.
- Known clinical or genetic diagnosis of dyskeratosis congenita
- Clonal cytogenetic abnormalities consistent with pre-myelodysplastic syndrome (pre- MDS) or MDS on marrow examination (e.g. Monosomy 7).
- Diagnosis of myelodysplastic syndrome (MDS).
- Presence of anti-donor HLA antibodies (positive anti-donor HLA antibody is defined as a positive cross-match test of any titer by complement- dependent cytotoxicity or flow cytometric testing or the presence of anti- donor HLA antibody to the high expression loci HLA-A, B, C, DRB1, or DPB1 with mean fluorescence intensity (MFI) \geq 1000 by solid phase immunoassay).

... and 7 more (see full listing online)

Locations (1 total)

St. Jude Children's Research Hospital, Memphis, Tennessee, United States

<https://clinicaltrials.gov/study/NCT04558736>

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