Post-transplant cyclophosphamide-based graft-versus-host disease prevention following mismatched unrelated donor peripheral blood stem cell transplant: ACCESS trial preliminary results

A multi-center prospective CIBMTR® (Center for International Blood and Marrow Transplant Research®) study sponsored by NMDP℠

CIBMTR is a research collaboration between the Medical College of Wisconsin® and NMDP.

Study details:

The ACCESS trial (NCT04904588) is designed to assess the effectiveness of post-transplant cyclophosphamide (PTCy) based graft-versus-host disease (GVHD) prevention on overall survival (OS) in mismatched unrelated donor (MMUD) allogeneic hematopoietic cell transplant (alloHCT). The trial aims to determine if OS using peripheral blood stem cells (PBSC) is similar to a prior trial using bone marrow.

The study includes 3 cohorts: 2 for adults based on conditioning intensity (myeloablative or reduced intensity conditioning [RIC]) and 1 pediatric using myeloablative conditioning. Accrual to the adult cohorts of the trial is complete, with over 200 patients in follow-up, while pediatric accrual continues. The first 70 adult patients enrolled in the RIC cohort were analyzed.

Results at a glance:

- **Enrollment and demographics:** Patients were treated at 13 transplant centers, with a median age of 65 years (50% male). Notably, 52% were racially or ethnically diverse.
- **Cancer types:** Patients received transplants for acute myeloid leukemia (53%), myelodysplastic syndromes (26%), acute lymphoblastic leukemia (7%) and other blood cancers (14%).
- **Donor information:** The median donor age was 25 years (56% female). HLA match levels were 7/8 (67%), 6/8 (27%), and 5/8 (6%).
- **Conditioning regimens:** RIC regimens primarily included fludarabine and melphalan (63%).
- **Survival and clinical outcomes:** 1-year OS was high at 79%. Rates of GVHD and other complications were comparable to those seen in HLA-matched donor HCT using PTCy.

Figure: Clinical endpoints at 1-year for the preliminary results of the ACCESS trial.

Clinical endpoint	One year estimate (%) (95%CI)#
GVHD-free, relapse free survival (GRFS)	47% (36-59%)
Primary graft failure by day 28	6% (2-14%)
Non-relapse mortality (NRM)	13% (6-22%)
Relapse	21% (13-32%)
Acute GVHD grade II-IV	43% (31-55%)*
Acute GVHD grade III-IV	9% (3-16%)*
NIH moderate/severe chronic GVHD	9% (3-17%)

*6-month estimate
#OS and GRFS using Kaplan-Meier method, NRM, relapse, and GVHD using cumulative incidence method.

Clinical impact:

The preliminary results from the ACCESS trial—which is part of the NMDP Donor for All initiative—demonstrate encouraging 1-year OS rates for patients receiving RIC MMUD PBSC alloHCT with PTCy. The study's findings suggest that MMUD HCT could significantly broaden the donor pool, ensuring that all patients in need of alloHCT, regardless of their racial or ethnic background, have access to this potentially life-saving treatment.

Scan to review more recent clinical research

Read the published abstract in the Journal of Clinical Oncology (DOI: 10.1200/JCO.2024.42.16_suppl.6503).

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