

Fludarabine Plus Melphalan Versus Addition of Venetoclax to Fludarabine/Melphalan Conditioning Regimen for Allogeneic Hematopoietic Stem Cell Transplantation in AML/MDS Patients Aged > 50 Years: a Multicenter, Randomized, Phase 3 Trial

NCT07396480

Status	RECRUITING
Phase	Phase 3
Sponsor	First Affiliated Hospital of Zhejiang University
Enrollment	186 participants

Key Eligibility Criteria

Inclusion (7)

- Aged \geq 50 years;
- Confirmed as acute myeloid leukemia (AML) in remission prior to transplantation, myelodysplastic syndrome (MDS; IPSS: Intermediate-2, high; or IPSS-R: Intermediate, high, very high; or IPSS-M: moderate-high, high, and very high), or myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) by morphology, immunology, cytogenetics and molecular biology (MICM) typing;
- Having an eligible donor and scheduled to undergo allogeneic hematopoietic stem cell transplantation (Allo-HCT) from a related or unrelated donor;
- Karnofsky Performance Score \geq 70;
- Eastern Cooperative Oncology Group (ECOG) Performance Status \leq 3;
- ... and 2 more (see full listing online)

Exclusion (7)

- Complicated with severe cardiac insufficiency with a left ventricular ejection fraction (EF) $<$ 60%; or complicated with severe arrhythmia, and assessed by the investigator as unable to tolerate the intensive conditioning regimen;
- Complicated with severe pulmonary insufficiency (obstructive and/or restrictive ventilatory disorder), and assessed by the investigator as unable to tolerate the intensive conditioning regimen;
- Complicated with severe liver function impairment, with liver function indicators (alanine aminotransferase [ALT], total bilirubin [TBIL]) exceeding 3 times the upper limit of normal (ULN); and assessed by the investigator as unable to tolerate the intensive conditioning regimen;
- Complicated with severe renal insufficiency, with serum creatinine (Cr) exceeding 2 times the upper limit of normal (ULN); or with a 24-hour creatinine clearance rate (Ccr) $<$ 50 ml/min, and assessed by the investigator as unable to tolerate the intensive conditioning regimen;
- Suffering from severe active infection prior to transplantation, and assessed by the investigator as unable to tolerate the intensive conditioning regimen;
- ... and 2 more (see full listing online)

Locations (18 total)

The First Affiliated Hospital of Fujian Medical University, Fuzhou, Fujian, China
Nanfang Hospital Southern Medical University, Guangzhou, Guangdong, China
The First Affiliated Hospital of Zhengzhou University, Zhengzhou, Henan, China
... and 15 more locations

<https://clinicaltrials.gov/study/NCT07396480>

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