

A Phase I/II Study of CAR.70-Engineered IL15-Transduced Cord Blood-Derived NK Cells With TGF-beta Receptor 2 (TGFBR2) Knock Out in Conjunction With Lymphodepleting Chemotherapy for the Management of Relapsed/Refractory Myeloid Malignancies

NCT06930651

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	M.D. Anderson Cancer Center
Enrollment	42 participants

Key Eligibility Criteria

Inclusion (20)

- Diagnosis: Age 18-80 years with diagnosis of:
 - Relapsed or refractory AML or "treated secondary AML"
 - Patients with a mutation that is targetable with an FDA-approved targeted therapy should have received at least one on these agents. . "Treated secondary AML "includes patients with prior diagnosis of a myeloid neoplasm (e.g. MDS) who received hypomethylating agents for this disease and subsequently progressed to AML. These patients must have received all of the following: a hypomethylating agent + venetoclax and intensive chemotherapy (if a suitable candidate for intensive therapy). These patients may be enrolled at the time of AML diagnosis if they have already received all of the treatments above for their antecedent myeloid neoplasm.
 - MDS that is intermediate, high-risk or very-high risk by the Revised International Prognostic Scoring System (R-IPSS)
 - Bone marrow blasts must be $\geq 5\%$.
- ... and 15 more (see full listing online)

Exclusion (11)

- Active grade III-V cardiac failure as defined by the New York Heart Association Criteria
 - Active serious infection not controlled by oral or intravenous antibiotics (e.g. persistent fever or lack of improvement despite antimicrobial treatment).
 - Active central nervous system leukemia
 - Known human immunodeficiency virus (HIV) seropositive, unless well-controlled on stable doses of anti-retroviral therapy.
 - Known hepatitis B surface antigen seropositive or known or suspected active hepatitis C infection Note: Patients who have isolated positive hepatitis B core antibody (ie, in the setting of negative hepatitis B surface antigen and negative hepatitis B surface antibody) must have an undetectable hepatitis B viral load. Patients who have positive hepatitis C antibody may be included if they have an undetectable hepatitis C viral load.
- ... and 6 more (see full listing online)

Locations (1 total)

The University of Texas M. D. Anderson Cancer Center, Houston, Texas, United States

<https://clinicaltrials.gov/study/NCT06930651>

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