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DONOR-DERIVED CD7 CAR T CELLS FOR T-CELL ACUTE LYMPHOBLASTIC LEUKEMIA

Topic: 02. Acute lymphoblastic leukemia - Clinical

Keywords: Acute lymphoblastic leukemia, CAR-T, Immune therapy

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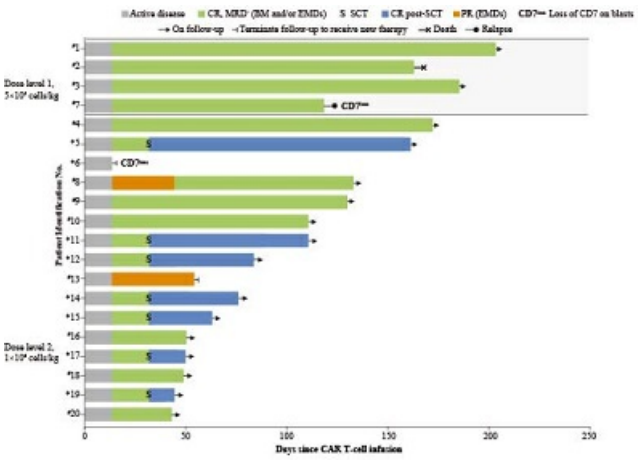
Background: Despite the success of chimeric antigen receptor T cell therapy in B cell malignances, there is currently no proved CAR T treatment for T cell neoplasms. We provide first evidence support the use of donor derived CAR T cells in T cell leukemia.

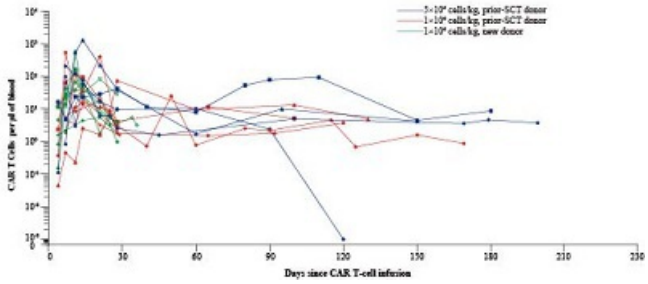
Aims: To assess the safety, tolerability, pharmacokinetic profile, and anti-tumor activity of donor-derived CD7 CAR T cells in patients with r/r T-ALL.

Methods: In this phase 1 trial, CD7 CAR T cells were manufactured with T cells from prior SCT prior to a single infusion at doses of 5 × 105 or 1 × 106 (± 30%) cells per kilogram of body weight. donors, or from new donors who were HLA-matched or haploidentical, via leukopheresis and transduced with a lentiviral vector which carries a CD7 CAR construct. The primary endpoint was safety. Short-term efficacy was also assessed.

Results: Results of 20 enrolled patients who received infusion are reported. Of 20 patients, 12 received previous HSCT-donor derived CAR T cells and 8 received fresh haplo-identical donor derived CAR T cells and plan to received transplantation as consolidation after remission.Adverse events included grade 3-4 hematologic toxicity in all (100%), grade 3-4 and grade 1-2 cytokine release syndrome in 2 (10%) and in 18 (90%), grade 1 neurotoxicity in 3 (15%), grade 1-2 graft-versus-host disease in 12 (60%), and grade 1 viral activation in 3 (15%) patients. Nineteen (95%) patients had a response, including 18 (90%) with complete remission and 1 (5%) with partial remission. Of 19 responders, 7 were bridged to SCT and remained minimal residual disease (MRD)-negative until last visit; 12 were followed up at a medium of 4.4 months, among whom 9 remained MRD-negative, 1 had a relapse, 1 discontinued for other treatment, and 1 died of pulmonary fungal infection at 5.5 months. CAR cells mostly persisted beyond 3 months. Patient CD7-positive healthy T cells were depleted, while CD7-negative T cells increased.

Image:





Summary/Conclusion: We report the initial toxicity profile and anti-leukemia activity of a donor-derived CD7-targeted cellular immunotherapy for patients with relapsed or refractory T-ALL. (Funded by the National Key R&D program; ChiCTR.org number, ChiCTR2000034762.)

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