A paciente apresentou estabilização clínica após início da terapia dirigida. **Conclusão:** DSA pré-transplante estão fortemente associados à falha de enxertia, especialmente em transplantes haploidênticos. Protocolos como o Ciurea viabilizam o procedimento ao superar essa barreira imunológica, porém acarretam imunossupressão por período mais prolongado. Estudos demonstram risco até duas vezes maior de infecções graves no primeiro ano pós-transplante nesses pacientes. A ocorrência precoce de bacteremia por *Listeria monocytogenes*, ainda no período pré-enxertia, evidencia tal vulnerabilidade. A listeriose é uma infecção rara, mas potencialmente grave em imunossuprimidos, podendo cursar com manifestações clínicas inespecíficas, como febre isolada, principalmente, nesse tipo de paciente. A identificação precoce e o início oportuno de cobertura antimicrobiana adequada são fundamentais, mesmo na ausência de sintomas específicos. Este relato demonstra a viabilidade do TCTH haploidêntico após dessensibilização de DSA em paciente com LMMC de alto risco. Ressalta-se, contudo, a necessidade de vigilância infecciosa rigorosa nesse contexto. A introdução precoce de antibióticos eficazes contra *Listeria monocytogenes* pode ser crucial para evitar desfechos desfavoráveis, dada sua gravidade potencial e apresentação clínica atípica.

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BICISTRONIC CD19/CD22 CAR T-CELL THERAPY EXHIBITS CLINICAL ACTIVITIES IN RELAPSED OR REFRACTORY CHILDHOOD B-CELL ACUTE LYMPHOBLASTIC LEUKEMIA

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Introduction: Our previous study on co-administration of CD19-and CD22-CAR T cell therapy demonstrated durable remission in children with relapsed or refractory B-lineage acute lymphoblastic leukemia (B-ALL) (Wang et al. J Clin Oncol 2023; 41:1670-83). To further improve outcomes, we developed a bicistronic CD19/CD22 CAR (B019) to aim at advancing event-free survival (EFS) and overall survival (OS) in the treatment of relapsed or refractory childhood B-ALL. The primary objectives were to enhance event-free survival, overall survival, and safety outcomes regardless of prior exposure to allogeneic hematopoietic cell transplantation. **Case report:** This single arm investigator-initiated trial enrolled 343 patients with relapsed or refractory B-ALL aged ≤ 18 years between January 2022 and April 2024. Patients underwent debulking and lymphodepletion during a 7-day period while the CAR T cells were manufactured. The regimen was administered at doses ranging from 1×10^6/kg to 10×10^6/kg. Patients were stratified into two main cohorts: (1) isolated extramedullary disease (n = 51) which included patients with isolated central nervous system (CNS) or testicular relapse; (2) refractory or combined hematologic relapse (n = 292), this cohort included patients who had bone marrow relapse with or without extramedullary involvement. Median follow-up for patients who were alive at the time of analysis was 13.9 months (IQR 9.0-22.4). Throughout the trial, we evaluated the patients' clinical responses, side effects, cytokine production assessment, bone marrow biopsies and the expansion and persistence of CAR-T cells at defined intervals. The response rate (CR+CRi) was 99.1% among the 318 evaluable patients, all of whom were MRD negative (< 0.01%). The 12-month EFS and OS rates for 267 patients with isolated or combined hematologic relapse were 72.4% and 91.4% respectively. Consolidative transplantation was associated with favorable outcomes and was performed in 37 of 267 patients (13.9%). The 12-month EFS was 86.0% for those who received transplantation versus 71.4% for those who did not (p = 0.04). However, regarding OS, the transplantation did not provide a significant benefit, with 12-month OS rates of 94.2% for transplanted patients and 92.2% for non-transplanted patients (p = 0.86). Among the 230 patients who did not undergo transplantation after CAR T-cell therapy, 69 patients relapsed with different loss of the antigens (45 CD19+/CD22+, 23 CD19-/CD22+, and 1 CD19-/CD22-). Most were treated with a second salvaged bicistronic CD19/CD22 CAR T cell therapy, achieving complete remission again in 35 of 36 (97.2%) CD19+/CD22+ patients and 14 of 21 (66.7%) CD19-/CD22+ patients. Cytokine release syndrome was the most common toxicity observed and was developed in all patients, with grade III-IV CRS occurring in 48.7% (155 patients), resulting in two deaths. CAR T-cell neurotoxicity was observed in 52 patients (16.4%) and manageable. No Other unexpected safety signals were observed during the study. **Conclusion:** Bicistronic CD19/CD22-targeted CAR-T cell therapy is a safe and effective regimen which achieved durable remission in children with relapsed or refractory B-ALL, including those with isolated or combined extramedullary relapse.

References: Trial Registration: Chinese Clinical Trial Registry, ChiCTR2000032211.

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BIOCURATIVOS BIOIMPRESSOS EM 3D CONTENDO CÉLULAS ESTROMAIS MESENQUIMAIS DE CORDÃO UMBILICAL HUMANO PRÉ-CONDICIONADAS COM 5-AZACITIDINA PARA TRATAMENTO DE FERIDAS CUTÂNEAS GRAVES EM MODELO MURINO DE ANEMIA FALCIFORME

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