

CD7 CAR-T Cell Sequential Allo-HSCT for Non-malignant Blood and Immune System Diseases

NCT06787560

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Zhejiang University
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (12)

- \. Non-malignant blood and immune system diseases include: hereditary bone marrow failure, congenital immune deficiency, hemoglobinopathy and other non-malignant blood and immune system diseases;
 - Confirmed hereditary bone marrow failure syndrome. Including: Fanconi anemia, congenital pure red cell aplastic anemia, congenital dyskeratosis, Scheuch-Day syndrome, congenital neutropenia, various bone marrow failure related congenital thrombocytopenia and other unclassified congenital bone marrow exhaustion diseases;
 - It meets the criteria of clinical manifestation, immune function and gene diagnosis of immune deficiency disease;
 - Diagnosed with hemoglobinopathy and dependent on blood transfusions; serum ferritin levels are $\leq 3000 \mu\text{g/L}$, with cardiac and hepatic iron content indicating moderate or lower iron overload; documentation of iron chelation therapy (including prescriptions or invoices) for at least three months prior to screening is available; no hydroxyurea, ruxolitinib, decitabine, or cytarabine has been administered in the three months preceding enrollment. The spleen size must not extend beyond the umbilical horizontal line or the midline of the abdomen. Allogeneic hematopoietic stem cell transplantation (allo-HSCT) is indicated, and suitable donors for related allo-HSCT are available.
 - \. Serum total bilirubin ≤ 1.5 times the upper limit of normal value, serum Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST) ≤ 3 times the upper limit of normal value range;
- ... and 7 more (see full listing online)

Exclusion (8)

- \. People with a history of epilepsy or other central nervous system disorders;
 - \. Epstein-Barr virus (EBV) DNA positive;
 - \. People with a history of prolonged QT interval or serious heart disease;
 - \. People with active hepatitis B or C virus;
 - \. Tuberculosis, AIDS and other major infectious diseases;
- ... and 3 more (see full listing online)

Locations (1 total)

The first affiliated hospital of medical college of zhejiang university, Hangzhou, Zhejiang, China

<https://clinicaltrials.gov/study/NCT06787560>

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