

Safety and Efficacy Study of CD19-CAR-DNT Cells in Autoimmune Diseases

NCT06316076

Status	RECRUITING
Phase	Phase 1
Sponsor	RenJi Hospital
Enrollment	48 participants

Key Eligibility Criteria

Inclusion (13)

- Voluntarily sign an ICF and expect to complete the study procedures for follow-up examinations and treatment;
- Aged 18 to 75 years (including cut-offs), regardless of gender;
- Appropriate organ function, and accordance with the following criteria within 7 days prior to lymphodepleting chemotherapy:
- Coagulation function: a) Fibrinogen ≥ 1.0 g/L; b) Activated partial thromboplastin time ≤ 1.5 times the upper limit of normal (ULN); c) Prothrombin time (PT) ≤ 1.5 times ULN;
- Liver function: a) Glutathione aminotransferase (AST) ≤ 3 times the upper limit of normal (ULN); b) Glutamic aminotransferase (ALT) ≤ 3 times ULN; c) Total bilirubin ≤ 1.5 times ULN, unless the subject has documented Gilbert syndrome. Subjects with Gilbert-Meulengracht syndrome with total bilirubin ≤ 1.5 times ULN may be included;
- ... and 8 more (see full listing online)

Exclusion (16)

- Individuals with a history of severe drug allergies or allergic constitution;
- Active infectious diseases: such as tuberculosis, central nervous system infection, hepatitis, enteritis, etc.;
- The following serious diseases: malignant tumor, end-stage renal failure, alveolar hemorrhage requiring mechanical ventilation, acute mononeuritis multiplex, or CNS involvement;
- Renal disease: creatinine clearance rate < 60 mL/min and serum creatinine > 1.5 times ULN within 1 week before lymphodepleting chemotherapy; Patients required hemodialysis or high-dose glucocorticoid therapy (e.g., prednisone (or equivalent) ≥ 100 mg per day) within 6 months before screening;
- Cardiovascular disease: unstable angina, cerebrovascular accident or transient ischemic attack, myocardial infarction, New York Heart Association class III or IV cardiac dysfunction, or refractory hypertension within 6 months before screening (refractory hypertension was defined as: on the basis of lifestyle modification, patients were treated with adequate and reasonably tolerable doses of ≥ 3 antihypertensive drugs (including diuretics) for > 1 month or with ≥ 4 antihypertensive drugs for effective blood pressure control) and a history of severe arrhythmia requiring drug treatment;
- ... and 11 more (see full listing online)

Locations (1 total)

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<https://clinicaltrials.gov/study/NCT06316076>

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