

Allogeneic CD19/BCMA CAR-T for B Cell-Related Autoimmune Disease

NCT07507201

Status	RECRUITING
Phase	Early Phase 1
Sponsor	The Children's Hospital of Zhejiang University School of Medicine
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (51)

- Major organ function must meet the following criteria (exceptions allowed for abnormalities related to autoimmune disease activity):
- Bone Marrow Function: a. Absolute neutrophil count (ANC) $\geq 1.0 \times 10^9/L$; b. Hemoglobin ≥ 60 g/L; c. Platelet count $\geq 30 \times 10^9/L$.
- Hepatic Function: ALT $\leq 3 \times$ ULN (except when elevation is attributable to inflammatory myopathy); AST $\leq 3 \times$ ULN (except when elevation is attributable to inflammatory myopathy); Total bilirubin $\leq 2.0 \times$ ULN ($\leq 3.0 \times$ ULN allowed for Gilbert syndrome).
- Renal Function: eGFR ≥ 30 mL/min/1.73 m². (Participants with eGFR < 30 mL/min/1.73 m² and/or those receiving renal replacement therapy may be considered eligible if, in the investigator's judgment, the potential benefit outweighs the risk and the participant or guardian provides fully informed consent.)
- Cardiac Function: Echocardiography shows no significant structural abnormalities and left ventricular ejection fraction (LVEF) $\geq 55\%$.

... and 46 more (see full listing online)

Exclusion (16)

- \. Subjects with known severe allergic reactions, hypersensitivity, contraindication to any medications during the trial (cyclophosphamide, tocilizumab), or subjects with a history of severe allergic reactions.
- Subjects with grade III or IV heart failure (NYHA classification).
- Have a history of congenital heart disease or acute myocardial infarction within 6 months prior to screening; Or severe arrhythmias (including multisource frequent supraventricular tachycardia, ventricular tachycardia, etc.); Or combined with moderate to massive pericardial effusion, serious myocarditis, etc; Or patients with unstable vital signs who need hypertensive drugs.
- \. Uncontrollable infection, or active infection that requires systemic treatment at screening.
- \. Had active pulmonary tuberculosis at screening.

... and 11 more (see full listing online)

Locations (1 total)

Children's Hospital, Zhejiang University School of Medicine, Hangzhou, Zhejiang, China

<https://clinicaltrials.gov/study/NCT07507201>

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