

Anti-CD19/BCMA CAR-NK Cells in Patients With B Cell Mediated Autoimmune Disease

NCT06792799

Status	RECRUITING
Phase	Early Phase 1
Sponsor	The Children's Hospital of Zhejiang University School of Medicine
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (27)

- Patients or their legal guardians must acknowledge the risks and procedures involved and subsequently provide informed consent to participate in the clinical trial.
- Predicted survival time \geq 12 weeks;
- ECOG: 0-2;
- Cardiac function: Left ventricular ejection fraction (LVEF) \geq 55% ;
- Renal function: eGFR \geq 30 mL/min/1.73 m² (For patients with an eGFR $<$ 30 mL/min/1.73 m² or those receiving renal replacement therapy, inclusion or exclusion in the study is determined at the discretion of the investigators.)

... and 22 more (see full listing online)

Exclusion (17)

- Subjects with known severe allergic reactions, hypersensitivity, contraindication to any medications during the trial (cyclophosphamide, fludarabine, obinutuzumab), or subjects with a history of severe allergic reactions
- Uncontrollable infection, or active infection that requires systemic treatment within 1 week prior to screening
- 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
- Renal replacement therapy has been or is being performed within 3 months prior to transfusion;

... and 12 more (see full listing online)

Locations (1 total)

Children's Hospital, Zhejiang University School of Medicine, Hangzhou, Zhejiang 310000, Hangzhou, Zhejiang, China