

Exploratory Clinical Study on the Safety and Efficacy of Anti-CD19/BCMA CAR-NK Cell Injection for the Treatment of Refractory Pediatric Rheumatic Diseases

NCT07490041

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

Key Eligibility Criteria

Inclusion (39)

- Gender unrestricted, age ≥5 years;
 - The patient or their legal guardian agrees to participate in this clinical trial and signs the informed consent form, indicating their understanding of the trial's purpose and procedures and willingness to participate;
 - Peripheral blood B cells confirmed by flow cytometry to express CD19, with a B cell count >5 cells/uL;
 - If previously treated with B cell-targeted therapy, peripheral blood B cell count at screening has returned to normal or above the pre-treatment level;
 - Echocardiography indicates basically normal cardiac structure and left ventricular ejection fraction (LVEF) $\geq 55\%$; electrocardiogram shows no significant abnormalities;
- ... and 34 more (see full listing online)

Exclusion (19)

- History of malignancy (except for basal cell or squamous cell skin cancer or carcinoma in situ of the cervix that has been excised and cured for at least 5 years), or current malignancy.
- Known allergy, hypersensitivity, intolerance, or contraindication to CD19/BCMA CAR-NK cells or any component of the drugs that may be used in the study (including fludarabine, cyclophosphamide, and tocilizumab), or subjects who have experienced a severe allergic reaction in the past.
- Evidence of severe active viral or bacterial infection, or uncontrolled systemic fungal infection at screening or baseline visits, or subjects with active or uncontrolled infection requiring parenteral antimicrobial therapy.
- Subjects with cardiac insufficiency classified as Class III or IV according to the New York Heart Association (NYHA) functional classification (see Appendix).
- Subjects with congenital heart disease, or history of acute myocardial infarction within 6 months prior to screening, or severe arrhythmia (including multifrequent ventricular premature beats, supraventricular tachycardia, ventricular tachycardia, etc.); or combined with moderate to large pericardial effusion, severe myocarditis, etc.; or unstable vital signs requiring vasopressors to maintain blood pressure.

... and 14 more (see full listing online)

Locations (1 total)

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

<https://clinicaltrials.gov/study/NCT07490041>

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