

Clinical Study of BCMA/CD70-targeted CAR-T Therapy for Refractory Pediatric Rheumatic Diseases

NCT07184450

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| Status | RECRUITING |
| Phase | Phase 1 |
| Sponsor | Chongqing Precision Biotech Co., Ltd |
| Enrollment | 11 participants |

Key Eligibility Criteria

Inclusion (23)

- Age e5 years old.
- To meet the diagnostic criteria of refractory B-cell-related pediatric rheumatic diseases, including but not limited to juvenile dermatomyositis, polyarticular juvenile idiopathic arthritis, systemic sclerosis, and primary Sjogren's syndrome.
- Diagnosed as juvenile dermatomyositis(JDM) according to the criteria of Bohan and Peter, and meeting the following conditions:
- The classification criteria of RJDM must meet (1) and any one of (2)-(5): (1) Patients who are intolerant or unresponsive to glucocorticoids and at least 2 immunosuppressants, and the duration of adequate hormone therapy should be at least 6 months; (2) The disease progresses rapidly and/or involves organs such as lungs, heart and gastrointestinal tract; (3) Calcification of subcutaneous or muscle and joint tissues; (4) Repeated rashes or skin ulcers; (5) Repeated or persistent myasthenia(muscle MRI indicates extensive, diffuse edema or the Childhood Myositis Assessment Scale(CMAS) should be less than 48 points, and at least two of the following five core measurement indicators should have abnormal results: Physician Global Assessment(PhGA) e2cm, Patient Global Assessment(PtGA) e2cm, Disease Activity Score(DAS) e2 points, Childhood Health Assessment Questionnaire(C-HAQ) e0.25 points, muscle enzyme level \> 1.5xupper limit of normal);
- RJDM with anti-synthetase syndrome who are positive for anti-synthetase antibody and those with immune-mediated necrotizing myopathy who are positive for SRP or HMGCRCR antibody can be included.

... and 18 more (see full listing online)

Exclusion (11)

- Severe major organ involvement related to the primary disease, such as severe pulmonary hypertension (PHA) (mean arterial pressure \> 45mmHg).
- primary immunodeficiency or severe secondary immunodeficiency that has not been corrected.
- accompanied by serious or active or uncontrollable infectious diseases, including but not limited to active tuberculosis, latent tuberculosis infection, active viral hepatitis,etc.
- Evidence of active malignant disease or diagnosis of malignant tumor(including hematological malignancies and solid tumors, except resected and cured skin basal cell carcinoma).
- Congenital heart disease or severe arrhythmias (including multisource frequent supraventricular tachycardia, ventricular tachycardia,etc.); Or combined with a large number of pericardial effusion, serious myocarditis, etc.;Or patients with unstable vital signs who need hypertensive drugs to maintain their blood pressure.

... and 6 more (see full listing online)

Locations (1 total)

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

<https://clinicaltrials.gov/study/NCT07184450>

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