

Clinical Trial of CD19-targeted CAR-T Therapy for Refractory Juvenile Dermatomyositis

NCT06569472

Status	RECRUITING
Phase	Phase 1
Sponsor	Chongqing Precision Biotech Co., Ltd
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (12)

- Age: ≥5 years and <17 years old
- To meet the diagnostic criteria of JDM, four or five of the following criteria must be met: ` symmetrical proximal muscle weakness; aCharacteristic skin changes, including positive dermatitis (purplish red rash on upper eyelid with periorbital edema) and Gottron papules (red patchy squamous papules on the back of knuckles); b The level of one muscle enzyme in serum was increased; c Positive myositis antibody; dElectromyography shows denervation and myopathy; e Muscle biopsies showed necrosis and inflammation.
- The classification criteria of RJDM must meet ` and any of the criteriaa-c: ` Patients who are intolerant or unresponsive to glucocorticoids and at least 2 immunosuppressants, adequate hormone therapy and duration of at least 6 months; a The disease progresses rapidly and/or involves organs such as lungs, heart and gastrointestinal tract; b Calcification of subcutaneous or muscle and joint tissues; c Repeated rashes or skin ulcers.
- myositis specific antibody positive, defined as MDA-5, NXP2, TIF-1³,Ro-52 and any other positive;
- The functions of important organs are basically normal:
... and 7 more (see full listing online)

Exclusion (15)

- Had previously received CAR T cell therapy;
- Have other autoimmune or rheumatic diseases other than JDM;
- primary immunodeficiency or severe secondary immunodeficiency that has not been corrected;
- accompanied by serious 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)
... and 10 more (see full listing online)

Locations (1 total)

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

<https://clinicaltrials.gov/study/NCT06569472>

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