

Safety and Efficacy of BAFF-R CART for Refractory Neuroimmune Diseases

NCT07022197

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Tianjin Medical University General Hospital
Enrollment	27 participants

Key Eligibility Criteria

Inclusion (6)

- \. Assessed by the investigator as having a refractory neuroimmune disease;
 - Refractory neuroimmune diseases were defined as:
 - Poor symptom control on at least three immunosuppressive agents for more than one year;
 - Clinical evidence of at least two relapses within 12 months or three relapses within 24 months and one relapse within 12 months prior to screening.
 - \. Male study participants must agree to use contraception during the treatment period for 1 year after receiving study treatment, and sperm donation is prohibited throughout the study period;
- ... and 1 more (see full listing online)

Exclusion (16)

- Any medical or psychiatric condition that, in the opinion of the investigator, may jeopardize the study participant or affect the study participant's ability to participate in this study;
 - A history of drug or alcohol abuse within the 12 months prior to baseline, or any condition that in the opinion of the investigator is associated with poor adherence;
 - Women who are breastfeeding or pregnant, or who plan to become pregnant at any time during the 12-month time period following treatment with CART, or a history of spontaneous or induced abortion within 4 weeks prior to screening;
 - Study participants with a clinically relevant active infection (e.g., sepsis, pneumonia, or abscess) or serious infection (resulting in hospitalization or requiring antibiotic therapy) within 4 weeks prior to baseline;
 - The study participant has received a live attenuated vaccination within 8 weeks prior to baseline; or is scheduled to receive a live vaccination (including COVID-19 vaccine) within 8 weeks after treatment;
- ... and 11 more (see full listing online)

Locations (1 total)

Tianjin Medical University General Hospital, Tianjin, Tianjin Municipality, China

<https://clinicaltrials.gov/study/NCT07022197>

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