

# Clinical Study on Targeted CD19/BCMA CAR-T Therapy for Autoimmune Diseases

NCT06775912

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<b>Status</b>	RECRUITING
<b>Phase</b>	Early Phase 1
<b>Sponsor</b>	Nanjing Bioheng Biotech Co., Ltd.
<b>Enrollment</b>	18 participants

## Key Eligibility Criteria

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### Inclusion (23)

- The subjects voluntarily participated in the study and signed the informed consent form.
  - Age  $\geq 18$  years old and  $\leq 70$  years old, both sexes.
  - Organ function and laboratory tests:
  - Liver function: alanine aminotransferase (ALT) and aspartate aminotransferase (AST)  $\leq 3 \times$  upper limit of normal (ULN), total bilirubin (TBIL)  $\leq 2 \times$ ULN (except Gilbert's syndrome).
  - Renal function: creatinine  $\leq 1.5 \times$ ULN or creatinine clearance  $\geq 40$  ml/min.
- ... and 18 more (see full listing online)

### Exclusion (7)

- SLE Patients: Those with uncontrolled lupus crisis within the 8 weeks prior to screening, including rapidly progressive lupus nephritis, severe neuropsychiatric lupus, severe hemolytic anemia, severe immune thrombocytopenia, agranulocytosis, severe cardiac damage, severe lupus pneumonia, severe lupus hepatitis, and severe vasculitis, as assessed by the investigator as unsuitable to participate in this study.
  - IIM Patients: Presence of severe rhabdomyolysis or CK levels  $\geq 120 \times$ ULN at screening.
  - Patients with severe asthma or Chronic Obstructive Pulmonary Disease (COPD) are eligible. Patients with mild or moderate asthma or COPD who are receiving stable treatment can also be enrolled.
  - There has been an active infection requiring systemic treatment within 2 weeks prior to the urethral irrigation, such as infectious pneumonia, tuberculosis, etc.
  - Positive for hepatitis B surface antigen (HBsAg), or positive for hepatitis B core antibody (HBcAb) with detectable hepatitis B virus (HBV) DNA in peripheral blood; positive for hepatitis C virus (HCV) antibody with detectable HCV RNA in peripheral blood; positive for human immunodeficiency virus (HIV) antibody; positive for syphilis antibody.
- ... and 2 more (see full listing online)

## Locations (1 total)

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The First People's Hospital of Lianyungang, Lianyungang, Jiangus, China