

Exploratory Clinical Study of Second-generation CD19/BCMA Chimeric Antigen Receptor NK Cell Injection in Treating Paediatric B Cell-related Autoimmune Diseases

NCT07283315

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| Status | RECRUITING |
| Phase | Early Phase 1 |
| Sponsor | The Children's Hospital of Zhejiang University School of Medicine |
| Enrollment | 12 participants |

Key Eligibility Criteria

Inclusion (48)

- Informed consent: The participant (and guardian if the participant is a minor) must provide written informed consent, indicating understanding of the study purpose and procedures and willingness to participate.
- Cardiac Function: Echocardiography shows no significant structural abnormalities and left ventricular ejection fraction (LVEF) \geq 55%.
- Hepatic Function: ALT \leq 3 \times ULN (except when elevation is attributable to inflammatory myopathy); AST \leq 3 \times ULN (except when elevation is attributable to inflammatory myopathy); Total bilirubin \leq 2.0 \times ULN (\leq 3.0 \times ULN allowed for Gilbert syndrome).
- Renal Function: eGFR \geq 30 mL/min/1.73 m². (Participants with eGFR $<$ 30 mL/min/1.73 m² and/or those receiving renal replacement therapy may be considered eligible if, in the investigator's judgment, the potential benefit outweighs the risk and the participant or guardian provides fully informed consent.)
- Pulmonary Function: No severe pulmonary disease, and SpO₂ \geq 92%.

... and 43 more (see full listing online)

Exclusion (15)

- Subjects with known severe allergic reactions, hypersensitivity, contraindication to any medications during the trial (cyclophosphamide, tocilizumab), or subjects with a history of severe allergic reactions.
- Uncontrollable infection, or active infection that requires systemic treatment at screening.
- Subjects with grade III or IV heart failure (NYHA classification).
- Have a history of congenital heart disease or acute myocardial infarction within 6 months prior to screening; Or severe arrhythmias (including multisource frequent supraventricular tachycardia, ventricular tachycardia, etc.); Or combined with moderate to massive pericardial effusion, serious myocarditis, etc; Or patients with unstable vital signs who need hypertensive drugs.
- Hepatitis B surface antigen (HBsAg) or hepatitis B core antibody (HBcAb) positive and peripheral blood hepatitis B virus (HBV) DNA titer greater than the normal reference value range; Or hepatitis C virus (HCV) antibody positive and peripheral blood hepatitis C virus (HCV) RNA titer greater than the normal reference value range; Or positive for human immunodeficiency virus (HIV) antibodies; Or syphilis test positive; Or cytomegalovirus (CMV) DNA test positive.

... and 10 more (see full listing online)

Locations (1 total)

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