

Study of Therapeutic Efficacy of CAR-T Cell Therapy in Patients With MDR-SRNS

NCT06553898

Status	RECRUITING
Phase	Phase 1
Sponsor	The Children's Hospital of Zhejiang University School of Medicine
Enrollment	18 participants

Key Eligibility Criteria

Inclusion (7)

- \. Age e2 years old, gender unlimited;
 - Diagnosed with SRNS according to the 2021 Kidney Disease: Improving Global Outcomes KDIGO Guidelines and have not achieved a complete response after 12 months of treatment with two standard doses of hormone replacement drugs with different mechanisms of action or relapse of disease activity after remission (at least one of the two drugs is a calcineurin inhibitor such as cyclosporine or tacrolimus; Other hormone replacement drugs include Mycophenolate Mofetil, cyclophosphamide, Taitaccept or rituximab); Or if no remission has been achieved after 3 to 6 months of adequate treatment with one calcineurin inhibitor, if the researcher judges that the benefits outweigh the risks and the patient or guardian has fully informed consent, the patient can be considered for inclusion. Patients with other diseases, such as systemic lupus erythematosus, requiring long-term systemic treatment with glucocorticoids or immunosuppressants, may be considered for inclusion after the investigator determines that the benefits outweigh the risks and the patient or guardian has fully informed consent;
 - \. Renal biopsy was performed and the pathological type was determined to be minimal lesion nephropathy(MCD) or focal segmental glomerulosclerosis (FSGS);
 - \. The functions of important organs are basically normal: Cardiac function: Left ventricular ejection fraction (LVEF) e55% with no obvious abnormality in electrocardiogram; Renal function: eGFR e30ML/min/1.73m2# Liver function: Asparagus cochinchinensis transaminase (AST) and Alanine Aminotransferase (ALT)d3.0 upper limit of normal, Total Bilirubin (TBIL) in serum d2.0xupper limit of normal; Lung function: No serious lung lesions, SpO2e92%;
 - \. Met the standards of leukapheresis or intravenous blood collection, No contraindication for cell collection;
- ... and 2 more (see full listing online)

Exclusion (15)

- \. Received CAR T cell therapy or other gene-modified cell therapy previously;
 - \. Patients had a cerebrovascular accident or seizure, or other active central nervous system disease within 6 months;
 - \. Genetic tests have confirmed hereditary kidney disease;
 - \. Renal biopsy has been confirmed as immunoglobulin A nephropathy, idiopathic membranous nephropathy or membranoproliferative glomerulonephritis;
 - \. Renal replacement therapy has been or is being performed within 3 months prior to transfusion. (if acute kidney injury factors were considered, patients with chronic kidney disease were excluded, and the benefits outweighed the risks as determined by the investigator and with the full and informed consent of the patient or guardian could be considered for inclusion);
- ... 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/NCT06553898>

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