

A Study of Anti-CD38 Monoclonal Antibody (SG301) Subcutaneous Injection in Children With Nephrotic Syndrome With Frequent Relapses or Steroid Dependence

NCT07087314

Status	RECRUITING
Phase	Phase 2
Sponsor	Mao Jianhua
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (7)

- Aged 6 - 18 years.
- Steroid-sensitive nephrotic syndrome with frequent relapses (FRNS) or steroid dependence (SDNS).
- Normal renal function: eGFR_{e90} ml/min/1.73m².
- After steroid treatment, morning urine protein <1 + or urine protein/creatinine <0.2 g/g (<20 mg/mmol) for e3 consecutive days.
- Within 7 days before enrollment, blood tests (without growth factors or transfusions) must meet: hemoglobin >80 g/L; platelets >75×10⁹/L; neutrophils >1.5×10⁹/L.
- ... and 2 more (see full listing online)

Exclusion (9)

- Family history of nephrotic syndrome, chronic glomerulonephritis, or uremia.
- Alanine aminotransferase >2×ULN or total bilirubin >2×ULN with a sustained increase for 2 weeks.
- HBsAg or HBcAb positive with Hepatitis B virus DNA above the lower limit of normal; Hepatitis C virus antibody - positive with Hepatitis C virus RNA positive; HIV antibody - positive.
- Chronic active infections (e.g., Epstein-Barr Virus, Cytomegalovirus, tuberculosis) that may worsen with steroids/ immunosuppressants.
- Acute active infection (excluding onychomycosis) requiring systemic antibiotics/antivirals.
- ... and 4 more (see full listing online)

Locations (1 total)

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