

The Efficacy and Safety of Biologics (Belimumab/Telitaccept) Induction Therapy in Proliferative Lupus Nephritis Patients for 6 Months Compared With Mycophenolate Mofetil Treatment

NCT07340463

Status	RECRUITING
Phase	Phase 2
Sponsor	Nanjing University School of Medicine
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (3)

- Signed written informed consent form. 2.Age 14-65 years (inclusive), any gender. 3.Meets the American College of Rheumatology (ACR) SLE diagnostic criteria (1997).
- All patients have biopsy-confirmed class III/IV ± V LN within the past six months.
- SLE-DAI score ≥ 6 . 6.Urine protein quantification ≥ 1.0 g/d.

Exclusion (9)

- Estimated glomerular filtration rate (eGFR) ≤ 45 ml/min/1.73 m². 2.Patients who have received renal replacement therapy, plasma exchange, immunoadsorption, or high-dose intravenous immunoglobulin (100g) within the past 2 months.
 - Patients with concomitant critical organ damage or lupus crisis (e.g., pulmonary hemorrhage, encephalopathy, heart failure) deemed unsuitable for clinical trial participation by the investigator.
 - Hematological abnormalities: White blood cells $< 3000/\mu\text{L}$ absolute neutrophil count $< 1500/\mu\text{L}$ or lymphocytes $< 800/\mu\text{L}$ platelet count $< 50,000/\mu\text{L}$ (unless due to SLE activity).
 - Liver function abnormalities: ALT, AST, or bilirubin levels exceeding 2 times the upper limit of normal.
 - Known allergy or contraindication to any component of belimumab and/or telitaccept.
- ... and 4 more (see full listing online)

Locations (1 total)

Clinical Research Ethics Committee of the General Hospital of Eastern Theater Command of the People's Liberation Army, Nanjing, Jiangsu, China

<https://clinicaltrials.gov/study/NCT07340463>

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