

Clinical Study of Rituximab Combined With Corticosteroids or Rituximab Monotherapy in the Treatment of Primary Membranous Nephropathy

NCT05514015

Status	RECRUITING
Phase	Phase 4
Sponsor	First Affiliated Hospital, Sun Yat-Sen University
Enrollment	78 participants

Key Eligibility Criteria

Inclusion (4)

- Men and women aged 18-75 years;
- Patients diagnosed as primary membranous nephropathy (PMN) by renal biopsy;
- After treatment with ACE inhibitors or ARBs for at least 3 months, the following two points were met (unless intolerance to ACE inhibitors or ARBs, contraindications, hypotension that may cause side effects, or the investigator judged that the patient was not suitable for RAS inhibitors):
 - (1) Those who have an average 24-hour urine protein ≤ 3.5 g twice a week, or an average 24-hour urine protein ≤ 5 g twice in 14 days, the requirement of RASi for at least 3 months is not required
 - (2) Blood pressure $\leq 130/80$ mmHg
 - (3) Glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73m² (calculated according to the CKD-EPI formula)
 - (4) If female, must be postmenopausal or postoperatively infertile or on medical contraception (considering the potential risk of thromboembolism in patients with kidney disease);
 - (5) Subjects voluntarily signed the informed consent form;

Exclusion (11)

- Patients with type 1 diabetes mellitus or type 2 diabetes mellitus complicated with diabetic nephropathy. Patients with a recent history of steroid-induced diabetes were eligible if renal biopsies show no evidence of secondary diabetic nephropathy within 6 months before the screening period
- Patients with secondary membranous nephropathy (such as hepatitis B and C, systemic lupus erythematosus, drug therapy, malignant tumors and other secondary causes);
- Previous treatment with rituximab, steroids, alkylating agents, calcineurin inhibitors, synthetic ACTH, mycophenolate (MMF), and azathioprine;
- Receipt of any other study medication (within the last month);
- Suspected or known allergy or immune reaction to rituximab, corticosteroids or any of their components (including excipients);
- ... and 6 more (see full listing online)

Locations (1 total)

Wei Chen, Guangzhou, Guangdong, China