

OBINOTUZUMAB Versus Cyclophosphamide + Glucocorticoids in Primary Membranous Nephropathy(Blossom Study)

NCT06781944

Status	RECRUITING
Phase	Phase 3
Sponsor	Huashan Hospital
Enrollment	144 participants

Key Eligibility Criteria

Inclusion (5)

- Aged 18^75 years (including 18 and 75)old at the time of signing Informed Consent Form
- pMN patients diagnosed according to renal biopsy (original biopsy needs to include light, immunofluorescence, and electron microscopy) within 5 years or serum anti-PLA2R antibody (e14 RU/ml)
- hour UPCR e 4 g/g and serum albumin (sALB) \< 30 g/L,despite being treated with ACEi and/or ARB for e 6 months prior to screening, or 24-hour UPCR e 5 g/g and sALB \< 30 g/L , despite being treated with ACEi and/or ARB for e 3 months prior to screening; or 24-hour UPCR e 8 g/g and sALB \< 25 g/L, despite being treated with ACEi and/or ARB for e 1 month prior to screening,.
- eGFR e40 mL/min/1.73m2 (CKD-EPI), a renal biopsy is required to exclude renal damage due to other co-morbidities if eGFR \<60mL/min/1.73 m2.
- Ability to comply with the study protocol, in the investigator's judgment

Exclusion (4)

- Patients with a secondary cause of MN (e.g. hepatitis B, systemic lupus erythematosus, medications, malignancies)
- Type 1 or 2 diabetes mellitus
- eGFR \<40 mL/min/1.73m2 (CKD-EPI) or dialysis or kidney transplantation
- Evidence of 50% reduction in proteinuria or serum anti-PLA2R antibody within 6 months prior to screening

Locations (1 total)

Huashan Hospital, Fudan University, Shanghai, Shanghai Municipality, China