

Clinical Study of Rituximab for the Treatment for Idiopathic Membranous Nephropathy with Nephrotic Syndrome

NCT05914155

Status	RECRUITING
Phase	Phase 3
Sponsor	Shoichi Maruyama MD PhD
Enrollment	88 participants

Key Eligibility Criteria

Inclusion (6)

- Patients who undergo kidney biopsy and are diagnosed as having idiopathic membranous nephropathy prior to the obtainment of informed consent
 - Patients who are diagnosed as having nephrotic syndrome prior to the obtainment of informed consent and receive no steroids or immunosuppressants within 12 weeks prior to the obtainment of informed consent
 - Patients with urine protein-creatinine ratio ≤ 3.5 g/gCr at the screening
 - Patients with hypoalbuminemia (serum albumin ≤ 3.0 g/dL) at the screening
 - Patients aged 15 years or older at informed consent
- ... and 1 more (see full listing online)

Exclusion (14)

- Patients with primary nephrotic syndrome other than membranous nephropathy (IgA nephropathy, minimal change disease, focal segmental glomerulosclerosis and so forth), and patients with secondary nephrotic syndrome (autoimmune disease, metabolic disease, infection, allergic/hypersensitive disease, tumor, and drug-induced disease)
 - Patients with the renal function lowered (eGFR < 30 mL/min/1.73 m² based on CKD-EPIcr formula) at the screening
 - Patients who have used anti-CD20 antibody including rituximab (genetical recombination) prior to the informed consent for idiopathic membranous nephropathy
 - Patients who have participated in another clinical study within 12 weeks prior to the informed consent (enrollment is allowed for those participating in a clinical study in the range of 'Indications' or 'Dosage and Administration' in Japan) or patients who are participating in another study
 - Patients with history of renal transplant
- ... and 9 more (see full listing online)

Locations (18 total)

Anjo Kosei Hospital, Anjo, Aichi-ken, Japan
Kasugai Municipal Hospital, Kasugai, Aichi-ken, Japan
Konan Kosei Hospital, KMnan, Aichi-ken, Japan
... and 15 more locations

<https://clinicaltrials.gov/study/NCT05914155>

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