

Rituximab Plus Cyclosporine in Idiopathic Membranous Nephropathy

NCT00977977

Status	RECRUITING
Phase	Phase 2
Sponsor	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (16)

- In order to be eligible to participate in this study, an individual must meet all of the following criteria:
- Stated willingness to comply with all study procedures and availability for the duration of the study
- Male or female, \geq 18 years of age
- Nephrotic range proteinuria that persists for at least 6 months post diagnosis of membranous nephropathy greater than 3.5 grams /24 hours (based on 24-hour urine collection).
- a. If the subject's renal function rapidly declines in less than 6 months could proceed with immunosuppression therapy sooner such as complications of the nephrotic syndrome that are not controlled with supportive therapy or evidence of decline in glomerular filtration rate or proteinuria >8 grams/day. Subjects with declining renal function and/or high-grade proteinuria due to MN are considered "high risk" subjects and have a higher probability of progression to end stage kidney disease.

... and 11 more (see full listing online)

Exclusion (15)

- An individual who meets any of the following criteria will be excluded from participation in this study:
- Estimated GFR <40 ml/min/1.73 m² from the preceding 2 months prior to enrollment while on ACEI/ARB therapy.
- Immunosuppressive medications or experimental medications of any type during the three-month period prior to initiating Rituximab and cyclosporine.
- Prior exposure to cyclosporine or tacrolimus for more than 6 months and/or evidence of intolerance or toxicity associated with cyclosporine treatment of any duration including irreversible azotemia, liver dysfunction or hypertension
- Rituximab use within the previous 12 months.

... and 10 more (see full listing online)

Locations (2 total)

National Naval Medical Center, Bethesda, Maryland, United States
National Institutes of Health Clinical Center, Bethesda, Maryland, United States

<https://clinicaltrials.gov/study/NCT00977977>

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