

Efficacy of Belimumab and Rituximab Compared to Rituximab Alone for the Treatment of Primary Membranous Nephropathy

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 18 to 75 years old - diagnosis of Membranous Nephropathy (MN) or Nephrotic Syndrome (study staff will review specific requirements) - hypertension while on maximum medications i.e. systolic BP greater than 140mmHg or diastolic greater than 90mmHg

Exclusion Criteria:

- Rituximab use within the previous 12 months - poorly controlled diabetes mellitus defined as hemoglobin A1c (HbA1c) 9.0% or greater - women of child-bearing age who are pregnant, nursing, or unwilling to be sexually inactive or use FDA-approved contraception for the duration of the study - additional medical and mental health exclusions apply, study staff will review

Conditions & Interventions

Interventions:

Drug: Belimumab, Drug: Placebo for Belimumab, Drug: Rituximab

Conditions:

Kidney, Prostate & Urinary

Keywords:

Clinics and Surgery Center (CSC), Membranous Nephropathy, Nephrotic Syndrome

More Information

Description: People with Primary MN lose more protein in their urine because the filters in their kidneys may be damaged. It is possible that some belimumab may also be lost in the urine because of this. This study will measure belimumab in the blood to decide if people with high urine protein should receive a higher dose of belimumab. Another purpose of this study is to help learn about whether the combination of belimumab and rituximab treatment is effective in making and keeping Primary MN inactive.

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Phase: PHASE2

IRB Number: STUDY00006831

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