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

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: 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

Conditions:
Kidney, Prostate & Urinary
Keywords:
Clinics and Surgery Center (CSC), Membranous Nephropathy, Nephrotic Syndrome

More Information

Description: This trial is a two-part study (Part A and Part B) of adults with primary membranous nephropathy, ages 18-75 inclusive. Part A is an open-label, PK phase to compare belimumab exposure between participants who have “low” proteinuria (≥ 4 to < 8 g/day) and “high” proteinuria (≥ 8 g/day) at Visit -1. Part B is a prospective, randomized, phase II, double-blind, placebo-controlled, multicenter clinical trial in adults with primary MN. Part B will commence after the analysis of the PK data in Part A.
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