A Double-Blind, Placebo-Controlled, Dose Escalation Study to Assess the Efficacy, Safety and Pharmacokinetics of Voclosporin in Adolescents with Lupus Nephritis

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Up to 18 years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 12 to 17 years old - diagnosis of systemic lupus erythematosus (SLE) - active lupus nephritis confirmed by a kidney biopsy

Exclusion Criteria:

- currently need dialysis - clinically significant active medical or mental health conditions (study staff will review) - certain medications, including: immunosuppression biologic agents, cyclophosphamide, calcineurin inhibitors (CNIs), start or change dose of ACE inhibitors/ARBs within 4 weeks prior to starting study, IV corticosteroids and IV immunoglobulin within 2 weeks of starting study

Conditions & Interventions

Conditions:
Immune Diseases, Kidney, Prostate & Urinary
Keywords:
Adolescent Lupus Nephritis, Lupus, Nephritis

More Information

Description: The aim of this study is to investigate whether voclosporin, added to standard treatment, is able to reduce activity of lupus nephritis over a study treatment period of 24 weeks, and to determine its safety as well as the best dose for treatment of lupus nephritis in children or adolescents.
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