A pivotal Phase 3, multicenter, randomized, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with focal segmental glomerulosclerosis (FSGS) who are receiving an angiotensin II receptor blocker (ARB)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 12-80 years old; - Primary FSGS, genetic FSGS or FSGS of undetermined cause - Receiving an ARB, or willing to take one for the study - see link to clinicaltrials.gov for complete inclusion criteria

Exclusion Criteria:

- Secondary FSGS - Not previously treated with standard of care therapies (including steroids) - Unable to swallow oral medication - see clinical to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Conditions:
Kidney, Prostate & Urinary, Rare Diseases
Keywords:
Focal Segmental Glomerular Sclerosis, FSGS

More Information

Description: A clinical research study for primary focal segmental glomerulosclerosis (FSGS) or focal segmental glomerulosclerosis (FSGS) of undetermined cause in pediatric (12-17 years) and adult patients. Eligible participants will be assigned to receive either DMX-200 (repagermanium) or placebo (50/50 chance) over a treatment period, with total participation up to 28 month, with potential for participation in an Open Label Extension study period. The main purpose of this study is to see if DMX-200 reduces proteinuria and slows the loss of kidney function in those with FSGS.
Study Contact: Ariel Langenberger - lange820@umn.edu
Principal Investigator: Michelle Rheault
Phase: PHASE3
IRB Number: STUDY00024254