DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE 3 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF PLOZASIRAN IN ADULTS WITH SEVERE HYPERTRIGLYCERIDEMIA (SHASTA-3 STUDY)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- diagnosis of severe hypertriglyceridemia (SHTG) with fasting TG levels of ≥ 500 mg/dL - fasting low density lipoprotein-cholesterol (LDL-C) ≤130 mg/dL - willing to follow diet counseling and maintain a stable low-fat diet - on standard of care lipid-lowering medications (exception if medications aren't tolerated) - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- Body mass index (BMI) >45kg/m^2 - used any hepatocyte-targeted small interfering ribonucleic acid (siRNA) that targets lipids and/or triglycerides within the past year - diagnosis of familial chylomicronemia syndrome (FCS) (type 1 Hyperlipoproteinemia)

Conditions & Interventions

Interventions:
Drug: Placebo, Drug: Plozasiran Injection
Conditions:
Diabetes & Endocrine, Heart & Vascular, Prevention & Wellness
Keywords:
Clinics and Surgery Center (CSC), dyslipidemia, high triglycerides, hypertriglyceridemia, triglycerides

More Information

Description: The purpose of this clinical research study is to look at how safe and effective the study drug, plozasiran, is at lowering triglycerides in people with severe hypertriglyceridemia. Hypertriglyceridemia is a condition where there is too much of a certain kind of fat (called triglycerides) in the blood. In people with severe hypertriglyceridemia, the level of triglycerides is more than 3 times higher than the normal, healthy level. The purpose of this study is to learn how effective the study drug is when given to people with very high triglycerides.
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