

STRENGTH

NCT02104817

Principal Investigator: Dr. Vipin Khetarpal, MD (S. Washington Office)

Condition: Eligible Men or Women Considered High Risk for Atherosclerotic Cardiovascular Disease (CVD)

Drug: Epanova® (omega-3 carboxylic acids) vs. corn oil control

Official Title: A Long-Term Outcomes Study to Assess S-Tatin Residual Risk Reduction With EpaNova in High Cardiovascular Risk Patients With Hypertriglyceridemia (STRENGTH)

Sponsor: AstraZeneca

Purpose: The study is a randomized, double-blind, placebo-controlled (corn oil), parallel group design that will enroll approximately 13,000 patients with hypertriglyceridemia and low HDL and high risk for CVD to be randomized 1:1 to either corn oil + statin or Epanova + statin, once daily, for approximately 3-5 years as determined when the number of MACE outcomes is reached.

Inclusion Criteria:

1. Men or women, ≥ 18 years of age.
2. Patient must be on a stable diet and statin* therapy at least 4 weeks prior to randomization (Visit 2) and meet the following criteria:
 1. LDL-C < 100 mg/dL
 2. TG level ≥ 180 and < 500 mg/dL and HDL-C < 42 mg/dL for men or HDL-C < 47 mg/dL for women
3. Patient is at high risk for a future cardiovascular event if at least one of the following criteria (3a, 3b or 3c)* is present via patient history, physical exam, or medical records at the time of screening:
 1. Any atherosclerotic CVD as defined in protocol.
 2. History of diabetes mellitus (type 1 or 2) and ≥ 40 years of age for men and ≥ 50 years of age for women, plus one of the risk factors defined in protocol.
 3. Male patients > 50 years of age or females > 60 years of age, with at least one of the risk factors defined in protocol.

Exclusion Criteria:

1. Allergy or intolerance to omega-3 carboxylic acids, omega-3 fatty acids, omega-3-acid ethyl esters, or corn oil.
2. Use of fibrates, bile acid sequestrants, or niacin or its analogues (> 250 mg/day) within 4 weeks prior to Visit 2.
3. Statin naïve at Visit 1.

Source: <https://clinicaltrials.gov/ct2/show/NCT02104817>

Retrieved on: 7/7/2017