CANTOS

NCT01327846

Principal Investigators:

Dr. Peter Fattal, MD (Covenant)

Dr. Rao Gudipati, MD (St. Mary's of Michigan)

Condition: Atherosclerosis

Drug: Canakinumab vs. Placebo

Official Title: A Randomized, Double-blind, Placebo-controlled, Event-driven Trial of Quarterly Subcutaneous Canakinumab in the Prevention of Recurrent Cardiovascular Events Among Stable Post-myocardial Infarction Patients With Elevated hsCRP

Sponsor: Novartis Pharmaceuticals

Purpose: Main Study (CACZ885M2301): The purpose of the pivotal phase of this trial is to test the hypothesis that canakinumab treatment of patients with MI at least one month prior to study entry and elevated hsCRP will prevent recurrent cardiovascular events.
The purpose of the extension phase of the main study is to collect additional long-term safety data on continued exposure to canakinumab in patients who participated in the pivotal phase.

- Sub-study 1 (CACZ885M2301S1): The purpose of this sub-study is to evaluate the effect of quarterly subcutaneous canakinumab treatment for 24 months comparted with placebo on the carotid plaque burden measured by integrated vascular MRI in patients enrolled in the CACZ885M2301 study (**CANTOS**).
- Sub-study 2 (CACZ885M2301S2): The purpose of this **CANTOS** sub-study is to determine whether, in patients with type 2 diabetes participating in the **CANTOS** main study, canakinumab compared to placebo, on top of standard of care increases insulin secretion and insulin sensitivity.

Inclusion Criteria:

Main Study Inclusion Criteria:

- Written informed consent
- Male, or Female of non-child-bearing potential
- Age ≥ 18 years.
- Spontaneous MI at least 30 days before randomization. hsCRP ≥ 2 mg/L

Substudy 1 Inclusion:

- All Inclusion from Main Study
- Acquisition of evaluable baseline MRI images of bilateral carotid arteries by the imaging core laboratory

Substudy 2 Inclusion:

- All inclusion from Main Study
- T2D at baseline per Main protocol criteria and be on a stable anti-hyperglycemic medication for at least 4 weeks prior to the baseline OGTT test
- Willing to have the OGTT assessment started before 10 am

Exclusion Criteria:

Main Study Exclusion Criteria:

- Pregnant or nursing (lactating) women
- Women of child-bearing potential
- Any of the following concomitant diseases
- Planned coronary revascularization (PCI or CABG)
- Major non-cardiac surgical or endoscopic procedure within past 6 months
- Multi-vessel CABG surgery within the past 3 years
- Symptomatic patients with Class IV heart failure (HF) (New York Heart Association [NYHA].
- Uncontrolled hypertension

CANTOS

NCT01327846

Principal Investigators:

Dr. Peter Fattal, MD (Covenant)

Dr. Rao Gudipati, MD (St. Mary's of Michigan)

Main Study Exclusion Criteria (Continued):

- Uncontrolled diabetes
- History or evidence of active tuberculosis (TB) infection

Substudy 1 Exclusion

- All Main Exclusion Criteria
- Patients with prior history of carotid angioplasty, stenting, or carotid atherectomy
- Patients with contraindications to MRI examination (brain aneurysm clip, implanted neural stimulator, implanted cardiac pacemaker, pacemaker wires or defibrillator, prosthetic heart valves, cochlear implant, ocular foreign body or other implanted body, tattoos, implanted insulin pump, metal shrapnel or bullet)
- Patients prone to claustrophobia or known anxiety disorders
- BMI > 40 kg/m2

Substudy 2 Exclusion

- This sub-study does not have any additional exclusion criteria. Other protocol-defined inclusion/exclusion criteria may apply

Source: https://clinicaltrials.gov/ct2/show/NCT01327846
Retrieved on: 7/6/2017