

CANTOS



Canakinumab **A**nti-inflammatory **T**hrombosis **O**utcomes **S**tudy

CANTOS: Aims

Primary Goal

To determine whether long-term treatment with canakinumab (50 mg, 150 mg or 300 mg subcutaneous every three months) as compared to placebo will reduce rates of recurrent cardiovascular events among stable post-myocardial infarction patients who remain at elevated vascular risk as gauged by increased levels of hsCRP (≥ 2 mg/L) despite usual care, including statin therapy.

CANTOS: Study Population

Major Inclusion Criteria

- Have suffered a documented acute myocardial infarction at least 30 days before randomization
- Have completed any planned revascularization procedures associated with their initial infarction, and
- Have evidence of systemic inflammation on the basis of an hsCRP ≥ 2 mg/L despite the stable use of standard secondary prevention therapies, including statins

Major Exclusion Criteria

- Pregnant or nursing (lactating) women
- Women of child-bearing potential
- Multi-vessel coronary artery bypass surgery within the past 3 years
- Symptomatic class IV heart failure
- Uncontrolled hypertension or uncontrolled diabetes
- History of or at high risk for tuberculosis or HIV related disease
- Nephrotic syndrome, renal transplant, or eGFR < 30 mL/min/1.73m²
- Active or recurrent hepatic disease
- Prior malignancy other than basal cell skin carcinoma
- A requirement for live vaccines during the trial period
- History of alcohol or drug abuse

CANTOS: Major Endpoints

Primary Endpoint

- Rate of recurrent major cardiovascular events, defined as non-fatal myocardial infarction, non-fatal stroke, or cardiovascular death

Secondary Endpoints

- Total mortality
- Hospitalization for unstable angina requiring revascularization
- New onset diabetes

Exploratory Endpoints

- Venous thrombosis
- Atrial Fibrillation
- Stent Thrombosis
- Hospitalization for congestive heart failure

CANTOS Design: Canakinumab Anti-inflammatory Thrombosis Outcomes Study

Stable CAD (post MI), On Statin, ACE/ARB, BB, ASA, Persistent Elevation of hsCRP (≥ 2 mg/L)

N = 10,064

Randomized
Canakinumab 50 mg
SC q 3 months

Randomized
Canakinumab 150 mg
SC q 3 months

Randomized
Canakinumab 300 mg
SC q 3 months

Randomized
Placebo
SC q 3 months

Primary Endpoint: Nonfatal MI, Nonfatal Stroke, Cardiovascular Death

Secondary Endpoints: Total Mortality, New Onset Diabetes, Other Vascular Events

Exploratory Endpoints: DVT/PE; SVT; hospitalizations for CHF; PCI/CABG; biomarkers



CANTOS: Press release June 22, 2017

CANTOS study shows ACZ885 (canakinumab) reduces cardiovascular risk in people who survived a heart attack

Phase III CANTOS study met the **primary endpoint**, a composite of heart attack, stroke and cardiovascular death, showing that ACZ885 (canakinumab) in combination with standard of care therapy reduces cardiovascular risk in people with a prior heart attack and inflammatory atherosclerosis

Full results will be presented at ESC 2017 in Barcelona as a hot line session