

Record 1 of 2



The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full [disclaimer](https://clinicaltrials.gov/about-site/disclaimer) (<https://clinicaltrials.gov/about-site/disclaimer>) for details.

COMPLETED ⓘ

Cardiovascular Risk Reduction Study (Reduction in Recurrent Major CV Disease Events) (CANTOS)

ClinicalTrials.gov ID ⓘ NCT01327846

Sponsor ⓘ Novartis Pharmaceuticals

Information provided by ⓘ Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted ⓘ 2020-01-22

Study Details Tab

Study Overview

Brief Summary

Feedback



Main Study (CACZ885M2301): The purpose of the pivotal phase of this trial was to test the hypothesis that canakinumab treatment of patients with myocardial infarction (MI) at least one month prior to study entry and elevated hsCRP could 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 was to evaluate the effect of quarterly subcutaneous canakinumab treatment for 24 months compared 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 was 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 could increase insulin secretion and insulin sensitivity.

Detailed Description

Sub-study 1 and 2 were terminated prior to data collection from subjects. However, there is an ongoing extension trial where patients are receiving open-drug label.

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

Conditions

Atherosclerosis

Intervention / Treatment

- Drug: Canakinumab
- Drug: Placebo
- Drug: Standard of care

Other Study ID Numbers

- CACZ885M2301
- 2010-022970-14 (EudraCT Number)

Study Start (Actual) ⓘ

2011-04-11

Primary Completion (Actual) ⓘ

2017-03-28

Study Completion (Actual) ⓘ

2019-04-14

Enrollment (Actual) ⓘ

10066

Study Type ⓘ

Interventional

Phase ⓘ

Phase 3

Resource links provided by the National Library of Medicine

[Drug Information](#) (<https://dailymed.nlm.nih.gov/dailymed/>) available for: [Canakinumab](#) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Canakinumab>).

[Other U.S. FDA Resources](#) (<https://classic.clinicaltrials.gov/ct2/info/fdalinks>).

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Alabama Locations

 **Athens, Alabama, United States, 35611**
Novartis Investigative Site

-  **Birmingham, Alabama, United States, 35235-3424**
Novartis Investigative Site
-  **Birmingham, Alabama, United States, 35243**
Novartis Investigative Site
-  **Birmingham, Alabama, United States, 35294-2041**
Novartis Investigative Site

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](https://clinicaltrials.gov/study-basics/learn-about-studies) (<https://clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Main Study Inclusion Criteria:

- Written informed consent
- Male, or Female of non-child-bearing potential
- Age $\geq$ 18 years.
- Spontaneous MI at least 30 days before randomization. hsCRP $\geq$ 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

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
- Uncontrolled diabetes
- History or evidence of active tuberculosis (TB) infection
- Substudy 1 Exclusion
- All Main exclusion
- 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.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Analysis of Core Phase First CEC Confirmed Major Adverse Cardiovascular Events (MACE) and Its Components	Time to occurrence of CEC (Cardiovascular clinical events adjudication committee) confirmed MACE, which was a composite endpoint consisting of CEC confirmed CV death, CEC confirmed non-fatal MI, or CEC confirmed non-fatal stroke. Patients with the CEC adjudicated reason for death of "Unknown" were counted as CV (cardiovascular) death.	From randomization, to end of treatment plus 30 days, up to approximately 6 years
Substudy 1 (Core Phase): Change From Baseline in		24 months

Carotid Plaque Burden in the Bifurcation Region of the Index Carotid Artery		
Substudy 2 (Core Phase): Change From Baseline of the Insulin Secretion Rate (ISR) Relative to Glucose 0-30 Min Defined as $\Phi 30 = \text{AUCISR } 0\text{-}30 / \text{AUCGluc } 0\text{-}30$ Averaged Across the Year 3, 4, 5 Visits		From randomization up to approximately 6 years

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Patients With Core Phase CEC Confirmed CV Death, Non-fatal MI, Non-fatal Stroke, or Hospitalization for Unstable Angina Requiring Unplanned Revascularization	Occurrence of the composite cardiovascular endpoint consisting of cardiovascular death, non-fatal MI, non-fatal stroke or hospitalization for unstable angina requiring unplanned revascularization. MACE includes CV death, non-fatal MI and non-fatal stroke. CEC = Clinical Endpoints Committee	From randomization, to end of treatment plus 30 days, up to approximately 6 years

Patients With Core Phase New Onset Type 2 Diabetes Among Patients With Pre-diabetes at Randomization	Time to CEC confirmed new onset of type 2 diabetes among those with pre-diabetes at randomization (i.e. excluding those that are normoglycemic at baseline)	From randomization up to approximately 6 years
Core Phase All-cause Mortality, Non-fatal MI, or Non-fatal Stroke	Occurrence of the composite endpoint consisting of all-cause mortality, non-fatal IM, or non-fatal stroke	From randomization, to end of treatment plus 30 days, up to approximately 6 years
Core Phase All-cause Mortality	Number of participant deaths	From randomization, to end of treatment plus 30 days, up to approximately 6 years
Summary of Adverse Events (Core Phase)	Summary of Adverse Events (AEs) and Serious Adverse Events (SAEs) occurring during the double-blind Core phase of the study. AEs/SAEs are any signs or symptoms that occur during the study treatment.	From randomization, to end of treatment plus 30 days, up to approximately 6 years
Summary of Adverse Events (Extension Phase)	Summary of Adverse Events (AEs) and Serious Adverse Events (SAEs) occurring during the Extension phase of the study. AEs/SAEs are any signs or	From start of Extension phase, to end of treatment plus 30 days,

	symptoms that occur during the study treatment.	up to approximately 2 years
Substudy 1 (Core Phase): Change From Baseline of the Total Vessel Wall Area at Month 3 in the Bifurcation Region of the Index Carotid Artery		3 months
Substudy 1 (Core Phase): Mean Total Vessel Wall Area Across the Left and Right Carotid Artery at Month 3 and Month 24		24 months
Substudy 1 (Core Phase): Change From Baseline in Corresponding Total Vessel Wall Area in the Left and Right Carotid Arteries		24 months
Substudy 1 (Core Phase): The Existence of a Baseline Total Vessel Wall Area by Treatment Interaction as Well as the Consistency of the		24 months

Treatment Effect Across Subgroups		
Substudy 2 (Core Phase): Change From Baseline in Insulin Sensitivity Index		From randomization up to approximately 6 years
Substudy 2 (Core Phase): Change From Baseline in OGTT Stimulated Area Under Curve (AUC) 0-120 Min of Glucose Concentration, Insulin Concentration, Pro-insulin Concentration, and Insulin Concentration/Glucose Concentration Ratio		From randomization up to approximately 6 years
Substudy 2 (Core Phase): Change From Baseline in Fasting Pro-Insulin Concentration/Insulin Concentration Ratio		From randomization up to approximately 6 years
Substudy 2 (Core Phase): Change From Baseline in OGTT Stimulated Area Under the Curve (AUC) 0-120 Min of C-peptide Concentration		From randomization up to approximately 6 years

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

Novartis Pharmaceuticals

Collaborators ⓘ

No information provided

Investigators ⓘ

- Study Director: Novartis Pharmaceuticals, Novartis Pharmaceuticals

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

* Find [Publications about Study Results](#) and related [Pubmed Publications](#) in the “Results” section of the study record.

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ

2011-03-29

First Submitted that Met QC Criteria ⓘ

2011-03-31

First Posted (Estimated) ⓘ

2011-04-04

Results Reporting Dates

Results First Submitted ⓘ

2019-11-25

Results First Submitted that Met QC Criteria ⓘ

2020-01-10

Results First Posted ⓘ

2020-01-22

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2020-01-10

Last Update Posted ⓘ

2020-01-22

Last Verified ⓘ

2020-01

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

Cardiovascular Death
Myocardial Infarction

Stroke

Canakinumab

IL-1B

hsCRP

Additional Relevant MeSH Terms

Arteriosclerosis

Arterial Occlusive Diseases

Vascular Diseases

Cardiovascular Diseases

Atherosclerosis

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Yes

IPD Plan Description

Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies A U.S. FDA-Regulated Device Product

No

Study Documents

- [Study Protocol \(https://storage.googleapis.com/ctgov2-large-docs/46/NCT01327846/Prot_000.pdf\)](https://storage.googleapis.com/ctgov2-large-docs/46/NCT01327846/Prot_000.pdf) [PDF, 1.05MB, 2016-09-13]
- [Statistical Analysis Plan \(https://storage.googleapis.com/ctgov2-large-docs/46/NCT01327846/SAP_001.pdf\)](https://storage.googleapis.com/ctgov2-large-docs/46/NCT01327846/SAP_001.pdf) [PDF, 2.26MB, 2017-04-14]