

CACZ885M2301 Trial

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

Study Phase: III

PURPOSE

The purpose 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. A secondary hypothesis, that canakinumab treatment in patients with MI and pre-diabetes, will prevent new onset diabetes (NOD) will also be tested. The trial is pivotal for registration for canakinumab for cardiovascular risk reduction.

Inclusion Criteria

- Male and Female (of non-child-bearing potential) \geq 18 years of age at Visit 1.
- Written informed consent obtained before any study procedure performed
- Documented spontaneous MI diagnosed at least 30 days before randomization
- Have an hsCRP \geq 2mg/L at screening (visit 1)(which is a minimum of 28 days after qualifying MI or after any PCI performed separately from qualifying MI) on stable (at least 4 weeks) long term medications.

Exclusion Criteria

- Women of child-bearing potential.
- Planned PCI or CABG or any other major surgical procedure.
- Major non-cardiac surgical or endoscopic procedure within the past 6 months to Visit 1.
- Multi-vessel CABG surgery within the past 3 years.
- Uncontrolled Hypertension or Diabetes
- Known active hepatic disorder (including cirrhosis, hepatitis B and C.
- History of active, ongoing, chronic or recurrent infectious disease or evidence of active tuberculosis (TB) infection at Visit 1.
- Live vaccinations within 3 months prior to randomization or planned live vaccinations during the trial.

To inquire if you are eligible for this study or to hear more about it, please contact:

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