

IMPROVE IT Trial

Study to Establish the Clinical Benefit/Safety of Vytorin (Ezetimibe/Simvastatin Tablet) vs Simvastatin in Subjects with Acute Coronary Syndrome (IMProved Reduction of Outcomes: Vytorin Efficacy International Trial-IMPROVE IT)

Study Phase III

Purpose

This is a randomized, active-control, double-blind study of subjects with stabilized high0risk acute coronary syndrome (ACS). The primary objective is to evaluate the clinical benefit of Ezetimibe/Simvastatin Combination 10/40 (single tablet, under the brand VYTORIN in the United States) compared with Simvastatin 40mg. Clinical benefit will be defined at the reduction in the risk of the occurrence of the composite endpoint of CV death, major coronary events, and stroke.

The study population will include those who meet the following inclusion/exclusion criteria, some of which are:

Inclusion Criteria

- Demographics: >18 years of age.
- Signed & dated, written informed consent to participate in this study.
- Clinically stable subjects may be eligible to enroll within 10 days following hospital admission with high-risk acute coronary syndrome (either STEMI or Non-STEMI or unstable angina).
- Subjects not taking a statin must have an LDL-C of 125 mg/dl or less. Subjects taking a statin must have a LDL-C of 100 mg/dl or less.

Exclusion Criteria

- Pregnant or lactating woman, or intending to become pregnant
- Subjects with active liver disease or persistent unexplained serum transaminase elevation
- Subjects with a history of alcohol or drug abuse
- Subjects with a history of sensitivity to statin or ezetimibe
- A subject for whom discontinuation of existing lipid lowering regimen poses an unacceptable risk.

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

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