



Prairie

EDUCATION & RESEARCH COOPERATIVE

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IMPROVE IT

- Trial Sponsor:** Schering-Plough / Merck
- Principal Investigator:** Michael Kelley, MD
- Trial Name:** 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)
- Details:** This is a randomized, active-control, double-blind study of subjects with stabilized high-risk 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 40 mg. Clinical benefit will be defined as the reduction in the risk of the occurrence of the composite endpoint of CV death, major coronary events, and stroke.

Eligibility

Ages Eligible for Study: 18 years and above

Genders Eligible for Study: Both

Inclusion Criteria:

- 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 an LDL-C of 100 mg/dl or less.

Exclusion Criteria:

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