

## Scott & White Hospital & Clinics

### Clinical Research at Scott & White

**Study Title:** A Multicenter, Double-Blind, Randomized Study to Establish the Clinical Benefit and Safety of Vytorin (Ezetimibe/Simvastatin Tablet) vs Simvastatin Monotherapy in High-Risk Subjects Presenting With Acute Coronary Syndrome (IMPROVED Reduction of Outcomes: Vytorin Efficacy International Trial – IMPROVE IT)

**Project ID#:** 050275

**Department:** Cardiology

**Sponsor:** Schering Plough

#### **Brief Synopsis of the Study**

The purpose of this study is to compare two drugs, Ezetimibe/Simvastatin Combination 10/40mg (sold as Vytorin®) and Simvastatin 40mg (sold as Zocor®). We want to see how well each of these drugs can lower LDL-C (“bad” cholesterol) levels. Both Vytorin® and Zocor® are already approved by the US Food and Drug Administration (FDA) for lowering cholesterol levels in the blood.

#### **Who is eligible to participate in the study?**

People who have just recovered from a condition called Acute Coronary Syndrome (ACS).

#### **What may be involved/required for subject participation? (Visits, tests and/or logs, etc.)**

Subjects will be randomly placed (randomized) either in Group 1 and take active Vytorin, or Group 2 and take active Zocor. Placebos (pills that look like active drug but do not contain drug- ‘inactive pills’) will also be used in this study so that additional simvastatin (Zocor) may be given depending upon LDL-C levels. These placebos are used so that the study coordinator and principal investigator (study doctor) will remain blinded (won’t know who is getting additional Zocor). Study visits will occur approximately every 4 months; each visit will include a blood draw and vital signs. Physical examinations will be done yearly. The study will last at least 2 ½ years.

#### **For More Information Contact:**

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