



# Prairie

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## EDUCATION & RESEARCH COOPERATIVE

326 North 7th Street, Suite 101, Springfield, IL 62701 • (217) 544-6464 X 66044 • Fax: (217) 522-1206

### EARLY ACS

<b><u>Trial Sponsor:</u></b>	Schering-Plough
<b><u>Principal Investigator:</u></b>	Michael Kelley, MD
<b><u>Trial Name:</u></b>	Early Glycoprotein IIb/IIIa Inhibition: A Randomized, Placebo-Controlled Trial Evaluating the Clinical Benefits of Early Front-Loaded Eptifibatide in the Treatment of Patients With Non-ST-Segment Elevation Acute Coronary Syndrome
<b><u>Purpose:</u></b>	The purpose of this study is to see if early INTEGRILIN® (eptifibatide) therapy in patients with non-ST-segment elevation acute coronary syndrome (ACS) reduces the occurrence of death, heart attack and urgent cardiac intervention (surgery) compared to placebo.
<b><u>Details:</u></b>	This study will enroll patients who experience symptoms of acute coronary syndromes (experiencing chest pain at rest with episodes lasting at least 10 minutes and they are planned to undergo invasive surgical procedures after being given study drug for 12 to 96 hours. There are two different treatment groups in this study, approximately half of the patients will go to one or the other and the likelihood of receiving study drug vs. placebo is 50/50 (like tossing a coin). Medications that are standard of care will be provided to the patients (all patients will be given aspirin and hospital standard doses of one of two other blood thinning drugs Unfractionated Heparin (UFH) or enoxaparin). Which ones patients will receive is at the discretion of the Investigator.
<b><u>Phase:</u></b>	Phase III
<b><u>Study Type:</u></b>	Interventional
<b><u>Study Design:</u></b>	Treatment, Randomized, Double-Blind, Placebo Control, Parallel Assignment, Safety/Efficacy Study
<b><u>Study Arms:</u></b>	Two
<b><u>Expected Enrollment:</u></b>	10,500
<b><u>Study Start:</u></b>	May 2004
<b><u>Expected Completion:</u></b>	April 2006



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### **Eligibility:**

**Ages Eligible for Study:** 18 years and above

**Genders Eligible for Study:** Both

### **Inclusion Criteria:**

- Willing and able to give informed consent and comply with study procedures and follow-up through 1 year
- Able to be randomized into the trial within 12 hours of having symptoms of acute coronary syndromes.
- Experiencing chest pain at rest with episodes lasting at least 10 minutes, within 24 hours of randomizing into the trial and **have at least two of the following criteria:**
  1. Age >60 years old, have an abnormal electrocardiogram, and/or blood tests positive for heart damage
  2. Electrocardiogram changes (ECG)
  3. Elevated troponin (protein released in the blood stream in people suffering from acute coronary syndromes) levels that are higher than an upper limit of normal for the hospital

### **Or have all 3 of the following:**

- Prior history of cardiovascular disease
- Elevated troponin levels that are higher than the upper limit of normal for the hospital
- 50-59 years of age

### **Exclusion Criteria:**

- pregnancy (known or suspected)
- renal dialysis within 30 days prior to randomizing in study on either placebo or INTEGRILIN
- other serious illnesses or any condition that the investigator feels would pose a significant hazard to the patient if the investigational therapy was to be initiated
- Stroke, bleeding disorders, or recent surgery at randomization into the trial