EARLY ACS: Early Glycoprotein IIb/IIIa Inhibition in Patients With Non-ST-segment Elevation Acute Coronary Syndrome (Study P03684AM2)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
Duke Clinical Research Institute

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00089895

First received: August 17, 2004
Last updated: September 1, 2015
Last verified: September 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

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 occurence of death, heart attack and urgent cardiac intervention (surgery) compared to placebo (with delayed provisional use of eptifibatide).

Condition	Intervention	Phase
Myocardial Ischemia Acute Coronary Syndrome	Drug: Eptifibatide (Integrilin) Drug: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Early Glycoprotein IIb/IIIa Inhibition in Non-ST-segment Elevation Acute Coronary Syndrome: 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 (EARLY ACS)

Resource links provided by NLM:

MedlinePlus related topics: Heart Attack

Drug Information available for: Eptifibatide

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Incidence of the Composite of Death, Myocardial Infarction (MI), Recurrent Ischemia Requiring Urgent Revascularization (RI-UR), and Thrombotic Bail-out. [Time Frame: 96 hours after randomization] [Designated as safety issue: No]

Secondary Outcome Measures:

- Incidence of the Composite of Death/MI. [Time Frame: 30 days after randomization] [Designated as safety issue: No]

Enrollment:	9406
Study Start Date:	November 2004
Study Completion Date:	November 2008
Primary Completion Date:	November 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Eptifibatide Eptifibatide in addition to standard of care such as standard doses of aspirin, unfractionated heparin or low-molecular-weight heparin.	Drug: Eptifibatide (Integrilin) intravenous; 180 mcg/kg bolus followed by infusion of 2 mcg/kg/min for 12 to 96 hours (or longer if necessary to complete the 18- to 24-hour post-PCI infusion period, or up to 120 hours in patients who proceed to CABG [coronary artery bypass graft]); second bolus of 180 mcg/kg administered 10 minutes after first bolus. Other Names: • Integrilin • SCH 060936 • SCH 60936
Placebo Comparator: Placebo Placebo in addition to standard of care such as standard doses of aspirin, unfractionated heparin or low-molecular-weight heparin.	Drug: Placebo intravenous; delivery to match eptifibatide to maintain blind

Detailed Description:

This study will enroll patients who experience symptoms of acute coronary syndrome (experiencing chest pain at rest with episodes lasting at least 10 minutes) and who 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 each group 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 standard hospital doses of one of two other blood thinning drugs - unfractionated heparin (UFH) or low-molecular-weight heparin). Which one patients receive is at the discretion of the Investigator.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Willing and able to give informed consent and comply with study procedures and follow-up through 1 year.
- Plan to undergo an invasive strategy after receiving study drug for 12 to 96 hours.
- Able to be randomized into the trial within 12 hours of having symptoms of acute coronary syndrome.
- Experiencing symptoms of cardiac ischemia at rest (angina or anginal equivalent) with episode(s) lasting at least 10 minutes and have at least 2 of the following:
  - 60 years of age or more
  - Electrocardiogram changes (ECG)
  - Elevated troponin (protein released in the blood stream in people suffering from acute coronary syndrome) or CK-MB levels

- Or have all 3 of the following:
  - Prior history of cardiovascular disease
  - Elevated troponin or CK-MB levels
  - 50-59 years of age

Exclusion Criteria:

- pregnancy (known or suspected)
- renal dialysis within 30 days prior to randomizing in study
- 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 (hemorrhagic stroke at any time or non-hemorrhagic stroke within previous 7 days), central nervous system damage (such as neoplasm, aneurysm, intracranial surgery), bleeding disorders (including gastrointestinal bleeding), or recent major surgery or major trauma.
- History of certain hematologic problems following treatment with heparin or eptifibatide.
- Therapy with certain related drugs within a short time before randomization into the trial.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Kunadian V, Giugliano RP, Newby LK, Zorkun C, Guo J, Bagai A, Montalescot G, Braunwald E, Califf RM, Van de Werf F, Armstrong PW, Harrington R, Gibson CM. Angiographic outcomes with early eptifibatide therapy in non-ST-segment elevation acute coronary syndrome (from the EARLY ACS Trial). Am J Cardiol. 2014 Apr 15;113(8):1297-305. doi: 10.1016/j.amjcard.2014.01.404. Epub 2014 Jan 31.

De Ferrari GM, Fox KA, White JA, Giugliano RP, Tricoci P, Reynolds HR, Hochman JS, Gibson CM, Théroux P, Harrington RA, Van de Werf F, White HD, Califf RM, Newby LK. Outcomes among non-ST-segment elevation acute coronary syndromes patients with no angiographically obstructive coronary artery disease: observations from 37,101 patients. Eur Heart J Acute Cardiovasc Care. 2014 Mar;3(1):37-45. doi: 10.1177/2048872613489315. Epub 2013 May 9.

Kaul P, Tanguay JF, Newby LK, Hochman JS, Westerhout CM, Califf RM, Tricoci P, Gibson CM, Giugliano RP, Harrington RA, Van de Werf F, Armstrong PW. Association between bleeding and mortality among women and men with high-risk acute coronary syndromes: insights from the Early versus Delayed, Provisional Eptifibatide in Acute Coronary Syndromes (EARLY ACS) trial. Am Heart J. 2013 Oct;166(4):723-8. doi: 10.1016/j.ahj.2013.07.014. Epub 2013 Sep 5.

Bagai A, White JA, Lokhnygina Y, Giugliano RP, Van de Werf F, Montalescot G, Armstrong PW, Tricoci P, Gibson CM, Califf RM, Harrington RA, Newby LK. Routine early eptifibatide versus delayed provisional use at percutaneous coronary intervention in high-risk non-ST-segment elevation acute coronary syndromes patients: an analysis from the Early Glycoprotein IIb/IIIa Inhibition in Non-ST-Segment Elevation Acute Coronary Syndrome trial. Am Heart J. 2013 Sep;166(3):466-73. doi: 10.1016/j.ahj.2013.05.019. Epub 2013 Jul 25.

Klutstein MW, Westerhout CM, Armstrong PW, Giugliano RP, Lewis BS, Gibson CM, Lutchmedial S, Widimsky P, Steg PG, Dalby A, Zeymer U, Van de Werf F, Harrington RA, Newby LK, Rao SV. Radial versus femoral access, bleeding and ischemic events in patients with non-ST-segment elevation acute coronary syndrome managed with an invasive strategy. Am Heart J. 2013 Apr;165(4):583-590.e1. doi: 10.1016/j.ahj.2013.01.009. Epub 2013 Feb 22.

Ezekowitz JA, Bakal JA, Westerhout CM, Giugliano RP, White H, Keltai M, Prabhakaran D, Tricoci P, Van de Werf F, Califf RM, Newby LK, Armstrong PW. The relationship between meteorological conditions and index acute coronary events in a global clinical trial. Int J Cardiol. 2013 Oct 3;168(3):2315-21. doi: 10.1016/j.ijcard.2013.01.061. Epub 2013 Feb 14.

Pride YB, Mohanavelu S, Zorkun C, Kunadian V, Giugliano RP, Newby LK, Braunwald E, Califf RM, Harrington RA, Gibson CM; EARLY ACS Investigators. Association between angiographic complications and clinical outcomes among patients with acute coronary syndrome undergoing percutaneous coronary intervention: an EARLY ACS (Early Glycoprotein IIb/IIIa Inhibition in Non-ST-Segment Elevation Acute Coronary Syndrome) angiographic substudy. JACC Cardiovasc Interv. 2012 Sep;5(9):927-35. doi: 10.1016/j.jcin.2012.05.007.

Roe MT, White JA, Kaul P, Tricoci P, Lokhnygina Y, Miller CD, van't Hof AW, Montalescot G, James SK, Saucedo J, Ohman EM, Pollack CV Jr, Hochman JS, Armstrong PW, Giugliano RP, Harrington RA, Van de Werf F, Califf RM, Newby LK. Regional patterns of use of a medical

management strategy for patients with non-ST-segment elevation acute coronary syndromes: insights from the EARLY ACS Trial. Circ Cardiovasc Qual Outcomes. 2012 Mar 1;5(2):205-13. doi: 10.1161/CIRCOUTCOMES.111.962332. Epub 2012 Feb 28.

Wang TY, White JA, Tricoci P, Giugliano RP, Zeymer U, Harrington RA, Montalescot G, James SK, Van de Werf F, Armstrong PW, Braunwald E, Califf RM, Newby LK. Upstream clopidogrel use and the efficacy and safety of early eptifibatide treatment in patients with acute coronary syndrome: an analysis from the Early Glycoprotein IIb/IIIa Inhibition in Patients with Non-ST-Segment Elevation Acute Coronary Syndrome (EARLY ACS) trial. Circulation. 2011 Feb 22;123(7):722-30. doi: 10.1161/CIRCULATIONAHA.110.958041. Epub 2011 Feb 7.

Giugliano RP, White JA, Bode C, Armstrong PW, Montalescot G, Lewis BS, van 't Hof A, Berdan LG, Lee KL, Strony JT, Hildemann S, Veltri E, Van de Werf F, Braunwald E, Harrington RA, Califf RM, Newby LK; EARLY ACS Investigators. Early versus delayed, provisional eptifibatide in acute coronary syndromes. N Engl J Med. 2009 May 21;360(21):2176-90. doi: 10.1056/NEJMoa0901316. Epub 2009 Mar 30.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00089895 History of Changes
Other Study ID Numbers:	P03684
Study First Received:	August 17, 2004
Results First Received:	November 13, 2009
Last Updated:	September 1, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:

myocardial infarction	coronary artery bypass graph surgery (CABG)
acute coronary syndrome	catheterization
non-ST-segment elevation	angina
eptifibatide	ischemia
Integrilin	cardiac ischemia
glycoprotein IIb/IIIa inhibitor (GP IIb/IIIa)	cardiovascular disease
percutaneous coronary intervention (PCI)	

Additional relevant MeSH terms:

Acute Coronary Syndrome	Signs and Symptoms
Coronary Artery Disease	Vascular Diseases
Ischemia	Eptifibatide
Myocardial Ischemia	Krestin
Syndrome	Adjuvants, Immunologic
Angina Pectoris	Anti-Infective Agents
Arterial Occlusive Diseases	Antibiotics, Antineoplastic
Arteriosclerosis	Antineoplastic Agents
Cardiovascular Diseases	Antiviral Agents
Chest Pain	Hematologic Agents
Coronary Disease	Immunologic Factors
Disease	Interferon Inducers
Heart Diseases	Pharmacologic Actions
Pain	Physiological Effects of Drugs
Pathologic Processes	Platelet Aggregation Inhibitors

ClinicalTrials.gov processed this record on May 08, 2016

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Results First Received: November 13, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Myocardial Ischemia Acute Coronary Syndrome
Interventions:	Drug: Eptifibatide (Integrilin) Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

Patients in both treatment groups who were undergoing PCI could receive unblinded eptifibatide provisionally immediately before or during percutaneous coronary intervention (PCI) at the discretion of the investigator.

Reporting Groups

	Description
Eptifibatide	Eptifibatide in addition to standard of care which includes usage of aspirin, unfractionated heparin or low-molecular weight heparin.
Placebo	Placebo in addition to standard of care which includes usage of aspirin, unfractionated heparin or low-molecular weight heparin.

Participant Flow: Overall Study

	Eptifibatide	Placebo
STARTED	**4722** [1]	**4684** [1]
COMPLETED	**4687** [2]	**4642** [2]
NOT COMPLETED	**35**	**42**
Consent Withdrawn	**11**	**14**
Technical reason	**7**	**2**
Surgery	**0**	**1**
Bleeding	**0**	**2**
Physician Decision	**3**	**7**
Exclusion criteria met	**6**	**6**
Not otherwise specified	**4**	**8**
Missing	**4**	**2**

[1] Number of Subjects Randomized with Intent to Treat
[2] Number of Subjects treated

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Eptifibatide	Eptifibatide in addition to standard of care which includes usage of aspirin, unfractionated heparin or low-molecular weight heparin.
Placebo	Placebo in addition to standard of care which includes usage of aspirin, unfractionated heparin or low-molecular weight heparin.
Total	Total of all reporting groups

Baseline Measures

	Eptifibatide	Placebo	Total
Number of Participants [units: participants]	4722	4684	9406
Age [units: years] Mean (Standard Deviation)	66.4 (10.6)	66.7 (10.7)	66.6 (10.7)
Gender [units: participants]			
Female	1513	1462	2975
Male	3209	3222	6431

Outcome Measures

Hide All Outcome Measures

1. Primary: Incidence of the Composite of Death, Myocardial Infarction (MI), Recurrent Ischemia Requiring Urgent Revascularization (RI-UR), and Thrombotic Bail-out. [Time Frame: 96 hours after randomization]

Measure Type	Primary
Measure Title	Incidence of the Composite of Death, Myocardial Infarction (MI), Recurrent Ischemia Requiring Urgent Revascularization (RI-UR), and Thrombotic Bail-out.
Measure Description	No text entered.
Time Frame	96 hours after randomization
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population

Reporting Groups

	Description
Eptifibatide	Eptifibatide in addition to standard of care which includes usage of aspirin, unfractionated heparin or low-molecular weight heparin.
Placebo	Placebo in addition to standard of care which includes usage of aspirin, unfractionated heparin or low-molecular weight heparin.

Measured Values

	Eptifibatide	Placebo
Number of Participants Analyzed [units: participants]	4722	4684
Incidence of the Composite of Death, Myocardial Infarction (MI), Recurrent Ischemia Requiring Urgent Revascularization (RI-UR), and Thrombotic Bail-out. [units: percentage of participants]	9.3	10.0

No statistical analysis provided for Incidence of the Composite of Death, Myocardial Infarction (MI), Recurrent Ischemia Requiring Urgent Revascularization (RI-UR), and Thrombotic Bail-out.

2. Secondary: Incidence of the Composite of Death/MI. [Time Frame: 30 days after randomization]

Measure Type	Secondary
Measure Title	Incidence of the Composite of Death/MI.
Measure Description	No text entered.
Time Frame	30 days after randomization
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population

Reporting Groups

	Description
Eptifibatide	Eptifibatide in addition to standard of care which includes usage of aspirin, unfractionated heparin or low-molecular weight heparin.
Placebo	Placebo in addition to standard of care which includes usage of aspirin, unfractionated heparin or low-molecular weight heparin.

Measured Values

	Eptifibatide	**Placebo**
Number of Participants Analyzed [units: participants]	**4722**	**4684**
Incidence of the Composite of Death/MI. [units: percentage of participants]	**11.2**	**12.3**

No statistical analysis provided for Incidence of the Composite of Death/MI.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Through hospital discharge or 120 hours after randomization, whichever occurred first.
Additional Description	No text entered.

Reporting Groups

	Description
Eptifibatide	Eptifibatide in addition to standard of care which includes usage of aspirin, unfractionated heparin or low-molecular weight

	heparin.
Placebo	Placebo in addition to standard of care which includes usage of aspirin, unfractionated heparin or low-molecular weight heparin.

Serious Adverse Events

	Eptifibatide	Placebo
Total, serious adverse events		
# participants affected / at risk	**66/4686 (1.41%)**	**60/4643 (1.29%)**
Blood and lymphatic system disorders		
ANAEMIA † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
MICROCYTIC ANAEMIA † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
Cardiac disorders		
PERICARDIAL EFFUSION † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
Ear and labyrinth disorders		
MIDDLE EAR INFLAMMATION † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
Endocrine disorders		
ADRENOCORTICAL INSUFFICIENCY ACUTE † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
Eye disorders		
OPHTHALMOPLEGIA † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
RETINAL ARTERY OCCLUSION † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
Gastrointestinal disorders		
ABDOMINAL PAIN † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
ABDOMINAL PAIN UPPER † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
DIARRHOEA † 1		
# participants affected / at risk	**2/4686 (0.04%)**	**0/4643 (0.00%)**
# events	**2**	**0**

DIVERTICULUM INTESTINAL † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
GASTRIC PERFORATION † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
GASTRIC ULCER HAEMORRHAGE † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
INTESTINAL ISCHAEMIA † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
OESOPHAGEAL ULCER † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
PANCREATITIS † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
General disorders		
ASTHENIA † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
IMPLANT SITE EFFUSION † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
INJECTION SITE PAIN † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
MULTI-ORGAN FAILURE † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**1/4643 (0.02%)**
# events	**1**	**1**
PYREXIA † 1		
# participants affected / at risk	**3/4686 (0.06%)**	**2/4643 (0.04%)**
# events	**3**	**2**
Hepatobiliary disorders		
CHOLANGITIS † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
CHOLECYSTITIS ACUTE † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**1/4643 (0.02%)**
# events	**1**	**1**
CHOLELITHIASIS † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
HEPATIC FAILURE † 1		

# participants affected / at risk	2/4686 (0.04%)	0/4643 (0.00%)
# events	2	0
LIVER DISORDER † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
Immune system disorders		
HYPERSENSITIVITY † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
Infections and infestations		
ABDOMINAL SEPSIS † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
ABSCESS LIMB † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
BRONCHITIS † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
CELLULITIS † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
ENDOCARDITIS † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
GASTROENTERITIS † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
HEPATITIS A † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
INFECTION † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
LOBAR PNEUMONIA † 1		
# participants affected / at risk	2/4686 (0.04%)	0/4643 (0.00%)
# events	2	0
LOWER RESPIRATORY TRACT INFECTION † 1		
# participants affected / at risk	1/4686 (0.02%)	1/4643 (0.02%)
# events	1	1
LUNG INFECTION † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
PERIRECTAL ABSCESS † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)

# events	0	1
PNEUMONIA † 1		
# participants affected / at risk	5/4686 (0.11%)	8/4643 (0.17%)
# events	5	8
POSTOPERATIVE WOUND INFECTION † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
PULMONARY TUBERCULOSIS † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
SEPSIS † 1		
# participants affected / at risk	2/4686 (0.04%)	3/4643 (0.06%)
# events	2	3
STAPHYLOCOCCAL SEPSIS † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
URINARY TRACT INFECTION † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
UROSEPSIS † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
Injury, poisoning and procedural complications		
LUMBAR VERTEBRAL FRACTURE † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
MEDICATION ERROR † 1		
# participants affected / at risk	0/4686 (0.00%)	4/4643 (0.09%)
# events	0	4
Investigations		
BLOOD CREATININE INCREASED † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
INTERNATIONAL NORMALISED RATIO DECREASED † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
Metabolism and nutrition disorders		
HYPERGLYCAEMIA † 1		
# participants affected / at risk	1/4686 (0.02%)	1/4643 (0.02%)
# events	1	1
Musculoskeletal and connective tissue disorders		
ARTHRALGIA † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
† 1		

MUSCULAR WEAKNESS		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
BLADDER CANCER † 1		
# participants affected / at risk	**2/4686 (0.04%)**	**0/4643 (0.00%)**
# events	**2**	**0**
COLON CANCER † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
GASTROINTESTINAL TRACT ADENOMA † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
HEPATIC NEOPLASM MALIGNANT † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
LUNG NEOPLASM MALIGNANT † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
Nervous system disorders		
BRAIN OEDEMA † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
CEREBRAL INFARCTION † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
ENCEPHALOPATHY † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**1/4643 (0.02%)**
# events	**1**	**1**
PARKINSONISM † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
SYNCOPE † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
VASCULAR ENCEPHALOPATHY † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
Psychiatric disorders		
CONFUSIONAL STATE † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**2/4643 (0.04%)**
# events	**1**	**2**
DELIRIUM † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**

# events	0	1
HALLUCINATION † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
Renal and urinary disorders		
IGA NEPHROPATHY † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
NEPHRITIS INTERSTITIAL † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
NEPHROPATHY TOXIC † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
NEPHROSCLEROSIS † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
RENAL FAILURE † 1		
# participants affected / at risk	6/4686 (0.13%)	4/4643 (0.09%)
# events	6	4
RENAL FAILURE ACUTE † 1		
# participants affected / at risk	6/4686 (0.13%)	5/4643 (0.11%)
# events	6	5
RENAL FAILURE CHRONIC † 1		
# participants affected / at risk	2/4686 (0.04%)	0/4643 (0.00%)
# events	2	0
RENAL INFARCT † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
Respiratory, thoracic and mediastinal disorders		
ANOXIA † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
BRONCHOSPASM † 1		
# participants affected / at risk	0/4686 (0.00%)	1/4643 (0.02%)
# events	0	1
COUGH † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
DYSPNOEA † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0
HYPOXIA † 1		
# participants affected / at risk	1/4686 (0.02%)	0/4643 (0.00%)
# events	1	0

LUNG DISORDER † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**1/4643 (0.02%)**
# events	**1**	**1**
PLEURAL EFFUSION † 1		
# participants affected / at risk	**2/4686 (0.04%)**	**0/4643 (0.00%)**
# events	**2**	**0**
PLEURAL FISTULA † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
PNEUMOTHORAX † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**1/4643 (0.02%)**
# events	**1**	**1**
PULMONARY CONGESTION † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
PULMONARY EMBOLISM † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**1/4643 (0.02%)**
# events	**1**	**1**
RESPIRATORY DISTRESS † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**2/4643 (0.04%)**
# events	**0**	**2**
RESPIRATORY FAILURE † 1		
# participants affected / at risk	**7/4686 (0.15%)**	**6/4643 (0.13%)**
# events	**7**	**6**
Vascular disorders		
AORTIC DISSECTION † 1		
# participants affected / at risk	**0/4686 (0.00%)**	**1/4643 (0.02%)**
# events	**0**	**1**
CIRCULATORY COLLAPSE † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**
PERIPHERAL EMBOLISM † 1		
# participants affected / at risk	**1/4686 (0.02%)**	**0/4643 (0.00%)**
# events	**1**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 11.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Through hospital discharge or 120 hours after randomization, whichever occurred first.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Eptifibatide	Eptifibatide in addition to standard of care which includes usage of aspirin, unfractionated heparin or low-molecular weight heparin.
Placebo	Placebo in addition to standard of care which includes usage of aspirin, unfractionated heparin or low-molecular weight heparin.

Other Adverse Events

	Eptifibatide	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/4686 (0.00%)**	**0/4643 (0.00%)**

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

- [x] The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- [ ] The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- [ ] Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Kunadian V, Giugliano RP, Newby LK, Zorkun C, Guo J, Bagai A, Montalescot G, Braunwald E, Califf RM, Van de Werf F, Armstrong PW, Harrington R, Gibson CM. Angiographic outcomes with early eptifibatide therapy in non-ST-segment elevation acute coronary syndrome (from the EARLY ACS Trial). Am J Cardiol. 2014 Apr 15;113(8):1297-305. doi: 10.1016/j.amjcard.2014.01.404. Epub 2014 Jan 31.

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Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00089895 History of Changes
Other Study ID Numbers:	P03684
Study First Received:	August 17, 2004
Results First Received:	November 13, 2009
Last Updated:	September 1, 2015
Health Authority:	United States: Food and Drug Administration

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For Patients and Families | For Researchers | For Study Record Managers