Protocol Registration Receipt
11/21/2012

Efficacy Of Eptifibatide Compared To Abciximab In Primary Percutaneous Coronary Intervention (PCI) For Acute ST Elevation Myocardial Infarction (STEMI)

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT00426751

Purpose

Multinational, multicentre, randomised, prospective, open, parallel group study directly comparing two glycoprotein-IIb/IIIa inhibitors, abciximab and eptifibatide, added early to standard treatment before primary PCI of STEMI patients with respect to effect on sum-ST-resolution after 60 minutes post-procedure and other measures of myocardial reperfusion

Condition	Intervention	Phase
Infarction, Myocardial	Drug: Abciximab	Phase 3

Condition	Intervention	Phase
	Drug: Eptifibatide	

Study Type: Interventional

Study Design: Treatment, Parallel Assignment, Open Label, Randomized, Efficacy Study

Official Title: Eptifibatide Versus Abciximab in Primary PCI for Acute ST Elevation Myocardial Infarction

Further study details as provided by GlaxoSmithKline:

Primary Outcome Measure:

- Number of Participants With Complete Sum ST Resolution (STR) 60 Minutes (Min) After Percutaneous Coronary Intervention (PCI) (Per Protocol Population) [Time Frame: Baseline (ECG I) and 60 min +/- 15 min after PCI (ECG III)] [Designated as safety issue: No]

  Sum STR was calculated as the difference between baseline (ECG I) and ECG III. The sum STR is the segment elevation resolution from all ECG leads associated with the infarct location. ST resolution, a method used to evaluate myocardial reperfusion, was expressed as a percentage of the baseline value (Complete: ≥ 70% resolution).
- Number of Participants With Complete Sum ST Resolution (STR) 60 Min After Percutaneous Coronary Intervention (PCI) (Intent-to-Treat Population) [Time Frame: Baseline (ECG I) and 60 min +/- 15 min after PCI (ECG III)] [Designated as safety issue: No]

  Sum STR was calculated as the difference between baseline (ECG I) and ECG III. The sum STR is the segment elevation resolution from all ECG leads associated with the infarct location. ST resolution, a method used to evaluate myocardial reperfusion, was expressed as a percentage of the baseline value (Complete: ≥ 70% resolution).

Secondary Outcome Measures:

- Number of Participants With Complete or Partial Sum ST Resolution (STR) 60 Min After PCI [Time Frame: Baseline (ECG I) and 60 min +/- 15 min after PCI (ECG III)] [Designated as safety issue: No]

  Sum STR was calculated as the difference between baseline (ECGI) and ECG III. The sum STR is the segment elevation resolution from all ECG leads associated with infarct location. ST resolution, a method used to evaluate myocardial reperfusion, was expressed as a percentage of the baseline (Complete: ≥ 70% resolution; Partial: ≥ 30% and < 70% resolution; None: < 30% resolution).
- Number of Participants With Complete Single Lead ST Resolution (STR) 60 Min After PCI [Time Frame: Baseline (ECG I) and 60 min +/- 15 min after PCI (ECG III)] [Designated as safety issue: No]

  Single lead STR is calculated as the difference (as a percentage) between baseline (ECG I) and ECG III of either the ST elevation on one of the leads (II, III, aVF, V5, and V6) or the ST depression of one of the precordial leads (V1- V4), whichever lead showed the largest deviation either at baseline or at ECG III, respectively (Complete: ≥ 70%; Partial: ≥ 30% and <70%).
- Mean Change From Baseline in the Sum ST Resolution 60 Min After PCI [Time Frame: Baseline (ECG I) and 60 min +/- 15 min after PCI (ECG III)] [Designated as safety issue: No]

  Sum STR was calculated as the difference between baseline (ECGI) and ECG III. The sum STR is the segment elevation resolution from all ECG leads

associated with infarct location. ST resolution, a method used to evaluate myocardial reperfusion, was expressed as a percentage of the baseline.

- Mean Change From Baseline in Single Lead ST Resolution (STR) 60 Min After PCI [Time Frame: Baseline (ECG I) and 60 min +/- 15 min after PCI (ECG III)] [Designated as safety issue: No]

  Single lead STR is calculated as the difference between baseline (ECG I) and ECG III of either the ST elevation on one of the leads (II, III, aVF, V5, and V6) or the ST depression of one of the precordial leads (V1 -V4), whichever lead showed the largest deviation either at baseline or at follow-up, respectively. STR was expressed as a percentage from baseline.
- Mean Change From Baseline in the Sum ST Resolution (STR) Before PCI [Time Frame: Baseline (ECG I) and immediately prior to PCI (ECG II)] [Designated as safety issue: No]

  Mean sum STR was calculated as the difference between baseline (ECGI) and ECG II: the mean of the sum of ST elevation resolution from all ECG leads associated with infarct location. ST resolution was expressed as a percentage from baseline.
- Mean Maximum ST Deviation Existing (Max STE) 60 Min After PCI [Time Frame: 60 min +/- 15 min after PCI (ECG III)] [Designated as safety issue: No]

  Max STE is measured similarly to single-lead STR, but was not compared with the ST deviation on the baseline ECG I. It was the existing ST deviation on the single ECG lead of maximum ST deviation present at 60 minutes after the PCI (ECG III).
- Number of Participants With the Indicated Patency of Infarcted Vessels According to Thrombolysis in Myocardial Infarction (TIMI) Classification Before PCI [Time Frame: immediately before PCI] [Designated as safety issue: No]

  Number of participants with the respective patency of the infarcted vessels was evaluated by TIMI (Thrombolysis In Myocardial Infarction) flow grades (Grade 0 = No perfusion, Grade 1 = Penetration with minimal perfusion, Grade 2 = Partial perfusion, Grade 3 = Complete perfusion), as assessed by core angiography lab.
- Number of Participants With TIMI 3 Patency of Infarcted Vessels Following PCI [Time Frame: after PCI] [Designated as safety issue: No]

  The number of participants with TIMI grade 3 (complete perfusion) patency of the infarcted vessels following PCI, as assessed by core angiography lab, was measured.
- Mean Number of Corrected TIMI Frame Counts (cTIMI) Following PCI [Time Frame: after PCI] [Designated as safety issue: No]

  cTIMI frame counts (number of cineframes needed for dye to reach standardized distal landmarks in a coronary vessel; objective index of coronary blood flow) following PCI, as assessed by core angiography lab.
- Number of Participants With the Indicated Myocardial Blush Grade (TIMI Myocardial Perfusion Grade [TMPG]) After PCI [Time Frame: after PCI] [Designated as safety issue: No]

  The number of participants with the indicated myocardial blush grade (TMPG), used to assess the myocardial reperfusion in the infarcted myocardium following PCI (as assessed by the core angiography laboratory), was measured. Blush grades: 0 = failure of dye to enter the microvasculature; 1 = dye slowly enters but fails to exit the microvasculature; 2 = delayed entry and exit of dye from the microvasculature; 3: normal entry and exit of dye from the microvasculature. Blush that is of only mild intensity throughout the washout phase but fades minimally is also classified as grade 3.
- Combined Endpoint: Number of Participants With Events of Death, Re-myocardial Infarction (MI), and Urgent Target Vessel Revascularisation (UTVR) [Time Frame: Day 7 or hospital discharge; Day 30 after index-MI] [Designated as safety issue: No]

  The number of participants who died, experienced re-MI, or experienced UTVR (necessity of re-PCI of the target vessel or coronary artery bypass graft [CABG] because of recurrent ischaemic angina within 30 days after PCI) within the specified timeframe was measured.
- Number of Participants Who Died, and/or Experienced Re-MI and UTVR (Individually Counted) [Time Frame: Day 7 or hospital discharge; Day 30 after

index-MI] [Designated as safety issue: No]

The number of participants who died, and/or experienced re-MI or UTVR (individually counted) within the specified timeframe was measured.

- Number of Participants Who Experienced Stroke or Major Bleeding Complications [Time Frame: Day 7 or hospital discharge; Day 30 after index-MI] [Designated as safety issue: No]

  Number of participants who experienced stroke (hemorrhagic, non-hemorrhagic) or major bleedings (TIMI class: intracranial haemorrhage, spontaneous bleeding, bleeding at any instrumented site, retroperitoneal bleeding, or clinically significant overt haemorrhage associated with a drop in haematocrit of ≥ 15% or a drop in haemoglobin of ≥ 5 g/dL).
- Number of Participants Who Died and or Experienced Re-MI Until 6 Months After PCI [Time Frame: until 6 Month (Day 180) after index-MI] [Designated as safety issue: No]

  The number of participants who died and/or experienced re-MI within 6 month after PCI was measured.
- Number of Participants With Heart Failure Until 6 Months After PCI [Time Frame: until 6 Months (Day 180) after index-MI] [Designated as safety issue: No]

  The number of participants with heart failure within 6 month after PCI was measured.
- Number of Participants With Major Bleedings (TIMI Classification) [Time Frame: Day 7 or hospital discharge; Day 30 after index-MI] [Designated as safety issue: No]

  Number of participants with major bleedings (according to TIMI classification: intracranial haemorrhage, spontaneous bleeding, bleeding at any instrumented site, retroperitoneal bleeding, or clinically significant overt haemorrhage associated with a drop in haematocrit of ≥ 15% or a drop in haemoglobin of ≥ 5 g/dL) within the specified timeframe was measured.
- Number of Participants With Minor Bleedings (TIMI Classification) [Time Frame: Day 7 or hospital discharge; Day 30 after index-MI] [Designated as safety issue: No]

  The number of participants with minor bleedings (according to TIMI classification: clinically overt bleeding [e.g., gross haematuria or haematemesis) associated with a drop in haematocrit of ≥ 9% or a drop in haemoglobin of ≥ 3 g/dL) within the specified timeframe was measured.
- Mean Duration of Stay in the Ward [Time Frame: until 6 months after index-MI] [Designated as safety issue: No]

  Costs were measured as the duration of stay in the ward (outpatient, normal ward, and intensive care unit) within the specified timeframe was measured.

Enrollment: 429
Study Start Date: October 2006
Study Completion Date: December 2007
Primary Completion Date: December 2007

Arms	Assigned Interventions
Active Comparator: Abciximab Intravenous bolus of 0.25 mg/kg followed by continuous intravenous infusion of 0.125 mcg/kg/min (max. 10 mcg/min) for	Drug: Abciximab Intravenous bolus of 0.25 mg/kg followed by continuous intravenous infusion of 0.125 mcg/kg/min (max. 10 mcg/min) for 12 h after PCI.

Arms	Assigned Interventions
12 h after PCI.	
Experimental: Eptifibatide Intravenous bolus of 180 mcg/kg followed immediately by a continuous infusion of 2.0 mcg/kg/ min for 20-24 h after end of PCI, and a second bolus of 180 mcg/kg administered 10 min after the first bolus.	Drug: Eptifibatide Intravenous bolus of 180 mcg/kg followed immediately by a continuous infusion of 2.0 mdg/kg/ min for 20-24 h after end of PCI, and a second bolus of 180 mcg/kg administered 10 min after the first bolus. Other Names: Abciximab Eptifibatide

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both

Inclusion Criteria:

- Women must be postmenopausal (i.e.12 months without menstrual period), or surgically sterile, i.e. women of child bearing potential are not allowed to be included into the study. In cases of doubt a pregnancy test should be performed. (NB -post menopausal women currently receiving hormone replacement are permissible)
- Acute myocardial infarction < 12 h defined as:
    a. Angina or equivalent symptoms > 20 min and
    b. ST elevation in 2 contiguous ECG leads (= 2 mm precordial lead, = 1 mm limb lead). This ECG recording serves as baseline ECG, i.e. ECG I.
- Planned primary percutaneous coronary intervention
- The subject has given written informed, dated consent to participate in the study

Exclusion Criteria:

- Subjects not able to give informed consent
- Left Bundle Branch Block
- Thrombolytic therapy within 24 hours before randomization
- Oral anticoagulation with International Normalized Ratio (INR) > 2

- Known platelets < 100.000/µl or known hemorrhagic diathesis
- Stroke or Transient Ischemic Attack (TIA) within the past 6 months or any permanent residual neurological defect
- Evidence of an active gastrointestinal or urogenital bleeding
- Major surgery within 6 weeks
- History of allergic reaction to abciximab or eptifibatide or any component used in the study (including contrast media)
- Known severe renal (creatinine clearance <30ml/min) or hepatic insufficiency as well as Alanine transaminase (ALT)/aspartate transaminase (AST) elevations = 3xUpper limit normal (ULN); isolated AST-elevation is not considered an exclusion criteria from study participation
- Severe concomitant disease with life expectation < 1 year
- Subject has participated in any study using an investigational drug or device within 30 days or within 5 half-lives of the investigational drug (whichever is longer) of entry into this study.
- Subjects who will be inaccessible due to geographic or social factors during treatment or follow-up
- In France, a subject is neither affiliated with nor a beneficiary of a social security category.

Contacts and Locations

Locations

France

GSK Investigational Site
Alençon, France, 61014

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Investigators

Study Director:	GSK Clinical Trials	GlaxoSmithKline

More Information

Responsible Party:	GlaxoSmithKline
Study ID Numbers:	106915
Health Authority:	Germany: German Institute of Medical Documentation and Information

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Study Results

Participant Flow

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr

	Description
	after PCI

Overall Study

	Eptifibatide	Abciximab
Started	226	203
Completed	204	183
Not Completed	22	20
Adverse Event	8	1
Lost to Follow-up	7	6
Consent Withdrawn	0	1
Other Reasons	7	12

Baseline Characteristics

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Baseline Measures

	Eptifibatide	Abciximab	Total
Number of Participants	214	196	410
Age, Continuous [1] [units: years] Mean (Standard Deviation)	61.3 (12.5)	60.5 (12.7)	60.9 (12.6)
Gender, Male/Female [2] [units: participants]			
Female	50	39	89
Male	164	157	321

[1] Twelve participants in the eptifibatide group and 6 participants in the abciximab group were excluded from the Intent-to-Treat (ITT) and Per Protocol (PP) Populations due to uncertain infarct localization. One of these participants in the abciximab group had not received study medication and was also excluded from safety analysis. One additional participant in the abciximab group had not received study medication and was also excluded from safety analysis.

[2] Twelve participants in the eptifibatide group and 6 participants in the abciximab group were excluded from the Intent-to-Treat (ITT) and Per Protocol (PP) Populations due to uncertain infarct localization. One of these participants in the abciximab group had not received study medication and was also excluded from safety analysis. One additional participant in the abciximab group had not received study medication and was also excluded from safety analysis.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With Complete Sum ST Resolution (STR) 60 Minutes (Min) After Percutaneous Coronary Intervention (PCI) (Per Protocol Population)
Measure Description	Sum STR was calculated as the difference between baseline (ECG I)

	and ECG III. The sum STR is the segment elevation resolution from all ECG leads associated with the infarct location. ST resolution, a method used to evaluate myocardial reperfusion, was expressed as a percentage of the baseline value (Complete: ≥ 70% resolution).
Time Frame	Baseline (ECG I) and 60 min +/- 15 min after PCI (ECG III)
Safety Issue?	No

Analysis Population Description

Per Protocol (PP) Population: All randomized participants who received at least one dose of study drug, who had data that were fully evaluable for the primary endpoint, and who did not show any major protocol violation.

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	113	111
Number of Participants With Complete Sum ST Resolution (STR) 60 Minutes (Min) After Percutaneous Coronary Intervention (PCI) (Per Protocol	71	65

	Eptifibatide	Abciximab
Population) [units: participants]		

Statistical Analysis 1 for Number of Participants With Complete Sum ST Resolution (STR) 60 Minutes (Min) After Percutaneous Coronary Intervention (PCI) (Per Protocol Population)

Groups	Eptifibatide, Abciximab
Non-Inferiority/Equivalence Test	Yes
Method	
Median Difference (Final Values)	2.1
90% Confidence Interval	-8.5 to 12.8

Additional details about the analysis, such as null hypothesis and power calculation:

[Not specified.]

For the assessment of differences between both treatment groups, a generalized model (under binomial probability distribution), adjusted for center, was applied.

2. Primary Outcome Measure:

Measure Title	Number of Participants With Complete Sum ST Resolution (STR) 60 Min After Percutaneous Coronary Intervention (PCI) (Intent-to-Treat Population)
Measure Description	Sum STR was calculated as the difference between baseline (ECG I) and ECG III. The sum STR is the segment elevation resolution from all ECG leads associated with the infarct location. ST resolution, a method used to evaluate myocardial reperfusion, was expressed as a percentage of the baseline value (Complete: ≥ 70% resolution).
Time Frame	Baseline (ECG I) and 60 min +/- 15 min after PCI (ECG III)

Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population: All randomized participants who received at least one dose of study medication.

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	214	196
Number of Participants With Complete Sum ST Resolution (STR) 60 Min After Percutaneous Coronary Intervention (PCI) (Intent-to-Treat Population) [units: participants]	124	103

Statistical Analysis 1 for Number of Participants With Complete Sum ST Resolution (STR) 60 Min After Percutaneous Coronary Intervention (PCI) (Intent-to-Treat Population)

Groups	Eptifibatide, Abciximab
Non-Inferiority/Equivalence Test	Yes

Method	
Mean Difference (Final Values)	6.8
95% Confidence Interval	-3.0 to 16.6

Additional details about the analysis, such as null hypothesis and power calculation:

[Not specified.]

For the assessment of differences between both treatment groups a generalised model (under binomial probability distribution), adjusted for centre, was applied.

Other relevant estimation information:

Analysis based on the ITT population confirmed the results observed in the PP population.

3. Secondary Outcome Measure:

Measure Title	Number of Participants With Complete or Partial Sum ST Resolution (STR) 60 Min After PCI
Measure Description	Sum STR was calculated as the difference between baseline (ECGI) and ECG III. The sum STR is the segment elevation resolution from all ECG leads associated with infarct location. ST resolution, a method used to evaluate myocardial reperfusion, was expressed as a percentage of the baseline (Complete: ≥ 70% resolution; Partial: ≥ 30% and < 70% resolution; None: < 30% resolution).
Time Frame	Baseline (ECG I) and 60 min +/- 15 min after PCI (ECG III)
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	214	196
Number of Participants With Complete or Partial Sum ST Resolution (STR) 60 Min After PCI [units: participants]		
Complete sum STR(≥70%)	124	103
Complete or partial sum STR (≥30%)	180	154
Partial sum STR (≥30% and <70%)	56	51
No sum STR (<30%)	34	42

4. Secondary Outcome Measure:

Measure Title	Number of Participants With Complete Single Lead ST Resolution (STR) 60 Min After PCI
Measure Description	Single lead STR is calculated as the difference (as a percentage)

	between baseline (ECG I) and ECG III of either the ST elevation on one of the leads (II, III, aVF, V5, and V6) or the ST depression of one of the precordial leads (V1- V4), whichever lead showed the largest deviation either at baseline or at ECG III, respectively (Complete: ≥ 70%; Partial: ≥ 30% and <70%).
Time Frame	Baseline (ECG I) and 60 min +/- 15 min after PCI (ECG III)
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	214	196
Number of Participants With Complete Single Lead ST Resolution (STR) 60 Min After PCI [units: participants]	105	82

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in the Sum ST Resolution 60 Min After PCI
Measure Description	Sum STR was calculated as the difference between baseline (ECGI) and ECG III. The sum STR is the segment elevation resolution from all ECG leads associated with infarct location. ST resolution, a method used to evaluate myocardial reperfusion, was expressed as a percentage of the baseline.
Time Frame	Baseline (ECG I) and 60 min +/- 15 min after PCI (ECG III)
Safety Issue?	No

Analysis Population Description

ITT Population. Some participants were un-evaluable with regard to the primary endpoint and were counted as failures. These participants were excluded from this analysis.

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	198	183
Mean Change From Baseline in the Sum ST Resolution 60 Min After PCI [units: percent change] Mean (Standard Deviation)	71.6 (27.2)	66.3 (31.1)

6. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Single Lead ST Resolution (STR) 60 Min After PCI
Measure Description	Single lead STR is calculated as the difference between baseline (ECG I) and ECG III of either the ST elevation on one of the leads (II, III, aVF, V5, and V6) or the ST depression of one of the precordial leads (V1 -V4), whichever lead showed the largest deviation either at baseline or at follow-up, respectively. STR was expressed as a percentage from baseline.
Time Frame	Baseline (ECG I) and 60 min +/- 15 min after PCI (ECG III)
Safety Issue?	No

Analysis Population Description

ITT Population. Participants with unevaluable ECGs were excluded from analysis.

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus

	Description
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	176	167
Mean Change From Baseline in Single Lead ST Resolution (STR) 60 Min After PCI [units: percent change] Mean (Standard Deviation)	70.2 (25.5)	64.0 (28.7)

7. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in the Sum ST Resolution (STR) Before PCI
Measure Description	Mean sum STR was calculated as the difference between baseline (ECGI) and ECG II: the mean of the sum of ST elevation resolution from all ECG leads associated with infarct location. ST resolution was expressed as a percentage from baseline.
Time Frame	Baseline (ECG I) and immediately prior to PCI (ECG II)
Safety Issue?	No

Analysis Population Description

ITT Population. Participants who did not have an ECG II immediately before PCI were excluded from analysis.

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	145	120
Mean Change From Baseline in the Sum ST Resolution (STR) Before PCI [units: percent change] Mean (Standard Deviation)	25.9 (32.0)	21.2 (29.0)

8. Secondary Outcome Measure:

Measure Title	Mean Maximum ST Deviation Existing (Max STE) 60 Min After PCI
Measure Description	Max STE is measured similarly to single-lead STR, but was not compared with the ST deviation on the baseline ECG I. It was the existing ST deviation on the single ECG lead of maximum ST deviation present at 60 minutes after the PCI (ECG III).
Time Frame	60 min +/- 15 min after PCI (ECG III)
Safety Issue?	No

Analysis Population Description

ITT Population. Participants with unevaluable ECGs were excluded from analysis.

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	180	172
Mean Maximum ST Deviation Existing (Max STE) 60 Min After PCI [units: millimeters (mm)] Mean (Standard Deviation)	1.1 (1.1)	1.4 (1.4)

9. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Patency of Infarcted Vessels According to Thrombolysis in Myocardial Infarction (TIMI) Classification Before PCI
Measure Description	Number of participants with the respective patency of the infarcted vessels was evaluated by TIMI (Thrombolysis In Myocardial Infarction) flow grades (Grade 0 = No perfusion, Grade 1 = Penetration with

	minimal perfusion, Grade 2 = Partial perfusion, Grade 3 = Complete perfusion), as assessed by core angiography lab.
Time Frame	immediately before PCI
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	214	196
Number of Participants With the Indicated Patency of Infarcted Vessels According to Thrombolysis in Myocardial Infarction (TIMI) Classification Before PCI [units: participants]		
TIMI 3 patency before PCI	74	59

	Eptifibatide	Abciximab
TIMI 2/3 patency before PCI	85	67
TIMI 0/1 patency before PCI	117	123

10. Secondary Outcome Measure:

Measure Title	Number of Participants With TIMI 3 Patency of Infarcted Vessels Following PCI
Measure Description	The number of participants with TIMI grade 3 (complete perfusion) patency of the infarcted vessels following PCI, as assessed by core angiography lab, was measured.
Time Frame	after PCI
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	214	196
Number of Participants With TIMI 3 Patency of Infarcted Vessels Following PCI [units: participants]	145	137

11. Secondary Outcome Measure:

Measure Title	Mean Number of Corrected TIMI Frame Counts (cTIMI) Following PCI
Measure Description	cTIMI frame counts (number of cineframes needed for dye to reach standardized distal landmarks in a coronary vessel; objective index of coronary blood flow) following PCI, as assessed by core angiography lab.
Time Frame	after PCI
Safety Issue?	No

Analysis Population Description

ITT Population. Participants with un-evaluable angiographies were excluded from analysis.

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus

	Description
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	165	151
Mean Number of Corrected TIMI Frame Counts (cTIMI) Following PCI [units: number of frame counts] Mean (Standard Deviation)	25.3 (21.0)	23.6 (17.9)

12. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Myocardial Blush Grade (TIMI Myocardial Perfusion Grade [TMPG]) After PCI
Measure Description	The number of participants with the indicated myocardial blush grade (TMPG), used to assess the myocardial reperfusion in the infarcted myocardium following PCI (as assessed by the core angiography laboratory), was measured. Blush grades: 0 = failure of dye to enter the microvasculature; 1 = dye slowly enters but fails to exit the microvasculature; 2 = delayed entry and exit of dye from the microvasculature; 3: normal entry and exit of dye from the microvasculature. Blush that is of only mild intensity throughout the washout phase but fades minimally is also classified as grade 3.
Time Frame	after PCI
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	214	196
Number of Participants With the Indicated Myocardial Blush Grade (TIMI Myocardial Perfusion Grade [TMPG]) After PCI [units: participants]		
Myocardial blush Grade 3	64	54
Myocardial blush Grade 2	0	0
Myocardial blush Grade 1	98	96
Myocardial blush Grade 0	13	11
Not assessable	38	34

13. Secondary Outcome Measure:

Measure Title	Combined Endpoint: Number of Participants With Events of Death, Re-myocardial Infarction (MI), and Urgent Target Vessel Revascularisation (UTVR)
Measure Description	The number of participants who died, experienced re-MI, or experienced UTVR (necessity of re-PCI of the target vessel or coronary artery bypass graft [CABG] because of recurrent ischaemic angina within 30 days after PCI) within the specified timeframe was measured.
Time Frame	Day 7 or hospital discharge; Day 30 after index-MI
Safety Issue?	No

Analysis Population Description

Safety Population: All participants who received at least one dose of study medication.

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	226	201
Combined Endpoint: Number of Participants With Events of Death, Re-myocardial Infarction (MI), and Urgent Target Vessel Revascularisation (UTVR) [units: participants]		
Death, re-MI, or UTVR until day 7 or discharge	12	14
Death, re-MI, or UTVR until day 30	17	17

14. Secondary Outcome Measure:

Measure Title	Number of Participants Who Died, and/or Experienced Re-MI and UTVR (Individually Counted)
Measure Description	The number of participants who died, and/or experienced re-MI or UTVR (individually counted) within the specified timeframe was measured.
Time Frame	Day 7 or hospital discharge; Day 30 after index-MI
Safety Issue?	No

Analysis Population Description

Safety Population

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min)

	Description
	for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	226	201
Number of Participants Who Died, and/or Experienced Re-MI and UTVR (Individually Counted) [units: participants]		
Deaths until day 7 or discharge	8	7
Deaths until day 30	13	7
Re-MI until day 7 or discharge	0	3
Re-MI until day 30	0	5
UTVR until day 7 or discharge	5	8
UTVR until day 30	5	10

15. Secondary Outcome Measure:

Measure Title	Number of Participants Who Experienced Stroke or Major Bleeding Complications

Measure Description	Number of participants who experienced stroke (hemorrhagic, non-hemorrhagic) or major bleedings (TIMI class: intracranial haemorrhage, spontaneous bleeding, bleeding at any instrumented site, retroperitoneal bleeding, or clinically significant overt haemorrhage associated with a drop in haematocrit of ≥ 15% or a drop in haemoglobin of ≥ 5 g/dL).
Time Frame	Day 7 or hospital discharge; Day 30 after index-MI
Safety Issue?	No

Analysis Population Description

Safety Population

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	226	201
Number of Participants Who Experienced Stroke or Major Bleeding Complications [units: participants]		

	Eptifibatide	Abciximab
Stroke or major bleeding until day 7 or discharge	6	1
Stroke or major bleeding until day 30	6	2

16. Secondary Outcome Measure:

Measure Title	Number of Participants Who Died and or Experienced Re-MI Until 6 Months After PCI
Measure Description	The number of participants who died and/or experienced re-MI within 6 month after PCI was measured.
Time Frame	until 6 Month (Day 180) after index-MI
Safety Issue?	No

Analysis Population Description

Safety Population

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	226	201
Number of Participants Who Died and or Experienced Re-MI Until 6 Months After PCI [units: participants]	15	15

17. Secondary Outcome Measure:

Measure Title	Number of Participants With Heart Failure Until 6 Months After PCI
Measure Description	The number of participants with heart failure within 6 month after PCI was measured.
Time Frame	until 6 Months (Day 180) after index-MI
Safety Issue?	No

Analysis Population Description

Safety Population

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous

	Description
	intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	226	201
Number of Participants With Heart Failure Until 6 Months After PCI [units: participants]	23	22

18. Secondary Outcome Measure:

Measure Title	Number of Participants With Major Bleedings (TIMI Classification)
Measure Description	Number of participants with major bleedings (according to TIMI classification: intracranial haemorrhage, spontaneous bleeding, bleeding at any instrumented site, retroperitoneal bleeding, or clinically significant overt haemorrhage associated with a drop in haematocrit of ≥ 15% or a drop in haemoglobin of ≥ 5 g/dL) within the specified timeframe was measured.
Time Frame	Day 7 or hospital discharge; Day 30 after index-MI
Safety Issue?	No

Analysis Population Description

Safety Population

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	226	201
Number of Participants With Major Bleedings (TIMI Classification) [units: participants]		
Major bleedings (TIMI classification) until day 7	6	0
Major bleedings (TIMI classification) until day 30	6	1

19. Secondary Outcome Measure:

Measure Title	Number of Participants With Minor Bleedings (TIMI Classification)
Measure Description	The number of participants with minor bleedings (according to TIMI classification: clinically overt bleeding [e.g., gross haematuria or haematemesis) associated with a drop in haematocrit of ≥ 9% or a

	drop in haemoglobin of ≥ 3 g/dL) within the specified timeframe was measured.
Time Frame	Day 7 or hospital discharge; Day 30 after index-MI
Safety Issue?	No

Analysis Population Description

Safety Population

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	226	201
Number of Participants With Minor Bleedings (TIMI Classification) [units: participants]		
Minor bleedings (TIMI classification) until day 7	19	12
Minor bleedings (TIMI classification)	19	12

	Eptifibatide	Abciximab
until day 30		

20. Secondary Outcome Measure:

Measure Title	Mean Duration of Stay in the Ward
Measure Description	Costs were measured as the duration of stay in the ward (outpatient, normal ward, and intensive care unit) within the specified timeframe was measured.
Time Frame	until 6 months after index-MI
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Measured Values

	Eptifibatide	Abciximab
Number of Participants Analyzed	211	195
Mean Duration of Stay in the Ward [units: days] Mean (Standard Deviation)	8.0 (6.7)	9.7 (11.9)

Reported Adverse Events

Reporting Groups

	Description
Eptifibatide	Intravenous bolus of 180 micrograms (µg)/kilogram (kg) Eptifibatide followed immediately by a continuous infusion of 2 µg/kg/minute (min) for 20-24 hours (hr) after the end of percutaneous coronary intervention (PCI), and a second bolus of 180 µg/kg administered 10 min after the first bolus
Abciximab	Intravenous bolus of 0.25 mg/kg Abciximab followed by continuous intravenous infusion of 0.125 µg/kg/min (maximum 10 µg/min) for 12 hr after PCI

Serious Adverse Events

	Eptifibatide	Abciximab
Total # participants affected/at risk	24/226 (10.62%)	19/201 (9.45%)
Cardiac disorders		
Acute myocardial infarction †[A]		
# participants affected/at	0/226 (0%)	1/201 (0.5%)

	Eptifibatide	Abciximab
risk		
# events		
Angina pectoris † [A]		
# participants affected/at risk	2/226 (0.88%)	2/201 (1%)
# events		
Atrioventricular block complete † [A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Cardiac failure † [A]		
# participants affected/at risk	2/226 (0.88%)	0/201 (0%)
# events		
Cardiogenic shock † [A]		
# participants affected/at risk	4/226 (1.77%)	2/201 (1%)
# events		
In-stent coronary artery restenosis † [A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		

	Eptifibatide	Abciximab
Pericardial effusion †[A]		
# participants affected/at risk	0/226 (0%)	2/201 (1%)
# events		
Ventricular fibrillation †[A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
Ventricular tachycardia †[A]		
# participants affected/at risk	2/226 (0.88%)	0/201 (0%)
# events		
Congenital, familial and genetic disorders		
Ventricular septal defect †[A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Gastrointestinal disorders		
Gastrointestinal hemorrhage †[A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)

	Eptifibatide	Abciximab
# events		
General disorders		
General physical health deterioration †[A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
Malaise †[A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Non-cardiac chest pain †[A]		
# participants affected/at risk	1/226 (0.44%)	1/201 (0.5%)
# events		
Sudden death †[A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
Infections and infestations		
Bronchitis †[A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)

	Eptifibatide	Abciximab
# events		
Gastrointestinal infection † [A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
Pneumonia † [A]		
# participants affected/at risk	1/226 (0.44%)	1/201 (0.5%)
# events		
Sepsis † [A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Staphylococcal infection † [A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Tracheobronchitis † [A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Injury, poisoning and procedural complications		

	Eptifibatide	Abciximab
Coronary artery reocclusion †[A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
In-stent arterial restenosis †[A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
Post procedural haematoma †[A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
Metabolism and nutrition disorders		
Diabetes mellitus †[A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Musculoskeletal and connective tissue disorders		

	Eptifibatide	Abciximab
Intervertebral disc displacement † [A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
Musculoskeletal chest pain † [A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Prostate cancer † [A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
Nervous system disorders		
Cerebral hemorrhage † [A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		

	Eptifibatide	Abciximab
Ischaemic stroke †[A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Transient ischaemic attack †[A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
Reproductive system and breast disorders		
Testicular pain †[A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
Respiratory, thoracic and mediastinal disorders		
Acute pulmonary oedema †[A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Chronic obstructive pulmonary disease †[A]		

	Eptifibatide	Abciximab
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Dyspnoea † [A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Dyspnoea exertional † [A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Pneumonia aspiration † [A]		
# participants affected/at risk	0/226 (0%)	1/201 (0.5%)
# events		
Pneumothorax † [A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
Pulmonary oedema † [A]		
# participants affected/at risk	1/226 (0.44%)	1/201 (0.5%)
# events		

	Eptifibatide	Abciximab
Vascular disorders		
Aortic dissection † [A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		
Haemorrhage † [A]		
# participants affected/at risk	2/226 (0.88%)	0/201 (0%)
# events		
Shock † [A]		
# participants affected/at risk	1/226 (0.44%)	0/201 (0%)
# events		

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 2%

	Eptifibatide	Abciximab
Total # participants affected/at risk	49/226 (21.68%)	28/201 (13.93%)
Cardiac disorders		
Angina pectoris † [A]		
# participants affected/at risk	11/226 (4.87%)	5/201 (2.49%)

	Eptifibatide	Abciximab
# events		
Cardiac failure † [A]		
# participants affected/at risk	5/226 (2.21%)	0/201 (0%)
# events		
Ventricular extrasystoles † [A]		
# participants affected/at risk	7/226 (3.1%)	4/201 (1.99%)
# events		
Ventricular tachycardia † [A]		
# participants affected/at risk	9/226 (3.98%)	6/201 (2.99%)
# events		
Injury, poisoning and procedural complications		
Post procedural heamatoma † [A]		
# participants affected/at risk	12/226 (5.31%)	9/201 (4.48%)
# events		
Musculoskeletal and connective tissue disorders		
Back pain † [A]		

	Eptifibatide	Abciximab
# participants affected/at risk	5/226 (2.21%)	0/201 (0%)
# events		
Nervous system disorders		
Headache †[A]		
# participants affected/at risk	0/226 (0%)	4/201 (1.99%)
# events		

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

More Information

Certain Agreements:

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

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

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Limitations and Caveats:

Results Point of Contact:

Name/Official Title: GSK Response Center

Organization: GlaxoSmithKline
Phone: 866-435-7343
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