Clinical trial results:
Prospective, randomized and controlled clinical trial comparing i.v. bolus application of Abciximab to i.c.application of Abciximab during primary PCU in patients with acute ST-elevation myocardial infarction

Summary

EudraCT number	2007-007864-63
Trial protocol	DE
Global end of trial date	11 June 2012

Results information

Result version number	v1 (current)
This version publication date	21 September 2019
First version publication date	21 September 2019

Trial information

Trial identification

Sponsor protocol code	Abciximab-STEMI

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00712101
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Leipzig
Sponsor organisation address	Ritterstr. 26, Leipzig, Germany, 04109
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Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 May 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 June 2012
Global end of trial reached?	Yes
Global end of trial date	11 June 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To examine whether intracoronary abciximab bolus application with subsequent 12 hour intravenous infusion in addition to primary percutaneous coronary intervention is beneficial for patients with STEMI in comparison to standard i.v. bolus application with respect to 90-day mortality, reinfarction and new congestive heart failure

Protection of trial subjects:

Patients were closely monitored with regard to safety during the course of the study. In addition to the documentation of adverse events, the following safety parameters were recorded:
- Severe or life-threatening bleeding according to the GUSTO definition until the time of hospital discharge
- Severe cardiac arrhythmia (ventricular tachycardia, ventricular fibrillation) during administration of the abciximab bolus
- Hemodynamic compromise (> 15 mmHg systolic blood pressure drop) during abciximab bolus administration
- Infections presumably associated with abciximab administration.

Background therapy: -

Evidence for comparator:

Adjunctive intravenous abciximab administration is established to improve coronary microcirculationand to reduce major cardiac adverse events in with acute ST-elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention
(PCI).

Actual start date of recruitment	16 July 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 2065
Worldwide total number of subjects	2065
EEA total number of subjects	2065

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0

Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1120
From 65 to 84 years	878
85 years and over	67

Subject disposition

Recruitment

Recruitment details:

Between July, 2008, and April, 2011, 2065 patients from 22 German trial sites were enrolled to the AIDA STEMI trial.

Pre-assignment

Screening details:

Patients were eligible for the study if they are ≥18 years of age and have clinical symptoms of acute myocardial infarction of >30 minutes and <12 hours with specific ECG criteria for STEMI. The inclusion criteria represent the standard definition for STEMI. The exclusion criteria reflect known contraindications for abciximab use.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Abciximab i.c.

Arm description:

Abciximab bolus intracoronary

Arm type	Experimental
Investigational medicinal product name	Abciximab
Investigational medicinal product code	B01AC13
Other name	ReoPro
Pharmaceutical forms	Irrigation solution
Routes of administration	Intracoronary use

Dosage and administration details:

0.25 mg/kg body weight bolus i.c.
subsequently 0.125 µg/kg/min body weight i.v. continously with a maximum of 10 µg/kg/min

Arm title	Abciximab i.v.

Arm description:

Abciximab bolus intravenously

Arm type	Active comparator
Investigational medicinal product name	Abciximab
Investigational medicinal product code	B01AC13
Other name	ReoPro
Pharmaceutical forms	Irrigation solution
Routes of administration	Intravenous use

Dosage and administration details:

0.25 mg/kg body weight bolus i.v.
subsequently 0.125 µg/kg/min body weight i.v. continously with a maximum of 10 µg/kg/min

Number of subjects in period 1	Abciximab i.c.	Abciximab i.v.
Started	1032	1033
Completed	940	936
Not completed	92	97
Consent withdrawn by subject	35	31
Lost to follow-up	11	11
Protocol deviation	46	55

Baseline characteristics

Reporting groups	
Reporting group title	Abciximab i.c.
Reporting group description: Abciximab bolus intracoronary	
Reporting group title	Abciximab i.v.
Reporting group description: Abciximab bolus intravenously	

Reporting group values	Abciximab i.c.	Abciximab i.v.	Total
Number of subjects	1032	1033	2065
Age categorical Units: Subjects			
Adults (18-64 years)	546	574	1120
From 65-84 years	455	423	878
85 years and over	31	36	67
Age continuous Units: years			
arithmetic mean	63	63	
standard deviation	± 13	± 13	-
Gender categorical Units: Subjects			
Female	256	255	511
Male	776	778	1554
Killip class on admission Units: Subjects			
Killip 1	854	869	1723
Killip 2	95	76	171
Killip 3	29	26	55
Killip 4	17	26	43
na	37	36	73
Infarct-related artery Units: Subjects			
Left anterior descending	424	431	855
Right coronary artery	433	429	862
Left main	4	7	11
Bypass graft	2	3	5
Left circumflex	130	122	252
na	39	41	80
TIMI fl ow before PCI Units: Subjects			
TIMI 0	587	562	1149
TIMI I	125	158	283
TIMI II	154	143	297
TIMI III	114	110	224
na	52	60	112
Cardiovascular risk factors: present smoking			

Units: Subjects			
yes	400	426	826
no	528	492	1020
na	104	115	219
Cardiovascular risk factors: Hypertension Units: Subjects			
yes	707	684	1391
no	276	307	583
na	49	42	91
Cardiovascular risk factors: Hypercholesterolaemia Units: Subjects			
yes	382	413	795
no	588	549	1137
na	62	71	133
Cardovascular risk factors: Diabetes mellitus Units: Subjects			
yes	202	199	401
no	790	791	1581
na	40	43	83
Body-mass index Units: kg/m²			
arithmetic mean	28	28	
standard deviation	± 4.5	± 4.5	-
Symptom onset to PCI hospital admission Units: minute			
median	160	166	
inter-quartile range (Q1-Q3)	100 to 285	101 to 287	-
Admission-to-balloon-time Units: minute			
median	32	32	
inter-quartile range (Q1-Q3)	22 to 50	22 to 49	-

End points

End points reporting groups	
Reporting group title	Abciximab i.c.
Reporting group description: Abciximab bolus intracoronary	
Reporting group title	Abciximab i.v.
Reporting group description: Abciximab bolus intravenously	

Primary: Composite of all-cause death, reinfarction, new congestive heart failure	
End point title	Composite of all-cause death, reinfarction, new congestive heart failure
End point description: Composite of all-cause death, reinfarction, and new congestive heart failure at 90 days after randomization. All components of the combined clinical end point were adjudicated by a Clinical End points Committee (CEC), blinded to the patient's assigned treatment.	
End point type	Primary
End point timeframe: 90 days	

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	940	936		
Units: patients				
Patients with event	66	71		
Patients without event	874	865		

Attachments (see zip file)	Time to composite endpoint/Composite.JPG

Statistical analyses

Statistical analysis title	Primary: composite endpoint at 90 days
Comparison groups	Abciximab i.c. v Abciximab i.v.
Number of subjects included in analysis	1876
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.66
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	0.92

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.3

Secondary: Death

End point title	Death

End point description:

End point type	Secondary

End point timeframe:

90 days

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	940	936		
Units: patients				
dead	42	34		
alive	898	902		

Attachments (see zip file)	Time to death/Death.JPG

Statistical analyses

Statistical analysis title	Secondary: death at 90 days
Comparison groups	Abciximab i.c. v Abciximab i.v.
Number of subjects included in analysis	1876
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.41
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.97

Secondary: Reinfarction

End point title	Reinfarction

End point description:

End point type	Secondary

End point timeframe:

90 days

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	940	936		
Units: patients				
patients with event	18	17		
patients without event	922	919		

Attachments (see zip file)	Time to reinfarction/Reinfarction.JPG

Statistical analyses

Statistical analysis title	Secondary: reinfarction at day 90
Comparison groups	Abciximab i.c. v Abciximab i.v.
Number of subjects included in analysis	1876
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	2.06

Secondary: Congestive heart failure

End point title	Congestive heart failure

End point description:

End point type	Secondary

End point timeframe:

90 days

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	940	936		
Units: patients				
patients with event	23	38		
patients without event	917	898		

Attachments (see zip file)	Time to heart failure/HeartFailure.JPG

Statistical analyses

Statistical analysis title	Secondary: congestive heart failure at day 90
Comparison groups	Abciximab i.c. v Abciximab i.v.
Number of subjects included in analysis	1876
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.05
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.35
upper limit	1

Secondary: Composite of all-cause death, reinfarction, new congestive heart failure - long-term

End point title	Composite of all-cause death, reinfarction, new congestive heart failure - long-term

End point description:

End point type	Secondary

End point timeframe:

12 months

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	925	921		
Units: patients				
patients with event	85	90		
patients without event	840	831		

Statistical analyses

Statistical analysis title	Secondary: composite endpoint at 12 months
Comparison groups	Abciximab i.c. v Abciximab i.v.
Number of subjects included in analysis	1846
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.69
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.28

Secondary: Creatine kinase - area under the curve

End point title	Creatine kinase - area under the curve

End point description:

The infarct size is assessed indirectly by the area under the curve of the creatine kinase and creatine kinase–MB release for measurements every 8 hours for 48 hours. For missing values, linear interpolation is used.

End point type	Secondary

End point timeframe:

48 h

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	561	545		
Units: microkat per L				
median (inter-quartile range (Q1-Q3))	691 (361 to 1121)	694 (354 to 1172)		

Statistical analyses

Statistical analysis title	Secondary: creatine kinase AUC
Comparison groups	Abciximab i.c. v Abciximab i.v.
Number of subjects included in analysis	1106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.87
Method	Wilcoxon (Mann-Whitney)

Secondary: Creatine kinase MB - area under the curve

End point title	Creatine kinase MB - area under the curve

End point description:

The infarct size is assessed indirectly by the area under the curve of the creatine kinase and creatine kinase–MB release for measurements every 8 hours for 48 hours. For missing values, linear interpolation is used.

End point type	Secondary

End point timeframe:

48 h

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	333	318		
Units: microkat per L				
median (inter-quartile range (Q1-Q3))	69 (38 to 105)	71 (40 to 121)		

Statistical analyses

Statistical analysis title	Secondary: Creatine kinase-MB AUC
Comparison groups	Abciximab i.c. v Abciximab i.v.
Number of subjects included in analysis	651
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.19
Method	Wilcoxon (Mann-Whitney)

Secondary: ST segment resolution at 90 min

End point title	ST segment resolution at 90 min

End point description:

Improvement in tissue perfusion is assessed by serial electrocardiographic (ECG) measurements at 90 minutes (defined by the time point of the worst ECG before PCI) and at 24 hours after PCI. The ECG ST-segment resolution measurement is performed in the ECG core laboratory at the University of Leipzig–Heart Center by operators blinded to the patient's assigned treatment group. The sum of ST-

elevation is measured 20 milliseconds after the end of the QRS complex in the initial and the follow-up ECGs. The ST-segment resolution is expressed as percentage.

End point type	Secondary

End point timeframe:

90 min

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	851	815		
Units: percent				
median (inter-quartile range (Q1-Q3))	55 (25 to 77)	53 (21 to 75)		

Statistical analyses

Statistical analysis title	Secondary: ST-segment resolution at 90 min
Comparison groups	Abciximab i.c. v Abciximab i.v.
Number of subjects included in analysis	1666
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.36
Method	Wilcoxon (Mann-Whitney)

Secondary: ST segment resolution at 24 h

End point title	ST segment resolution at 24 h

End point description:

Improvement in tissue perfusion is assessed by serial electrocardiographic (ECG) measurements at 90 minutes (defined by the time point of the worst ECG before PCI) and at 24 hours after PCI. The ECG ST-segment resolution measurement is performed in the ECG core laboratory at the University of Leipzig–Heart Center by operators blinded to the patient's assigned treatment group. The sum of ST-segment elevation is measured 20 milliseconds after the end of the QRS complex in the initial and the follow-up ECGs. The ST-segment resolution is expressed as percentage.

End point type	Secondary

End point timeframe:

24 h

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	721	690		
Units: percent				
median (inter-quartile range (Q1-Q3))	67 (40 to 82)	66 (38 to 81)		

Statistical analyses

Statistical analysis title	Secondary: ST-segment resolution at 24 h
Comparison groups	Abciximab i.c. v Abciximab i.v.
Number of subjects included in analysis	1411
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.59
Method	Wilcoxon (Mann-Whitney)

Secondary: TIMI flow post-PCI

End point title	TIMI flow post-PCI

End point description:

Epicardial perfusion is assessed by the TIMI flow post-PCI to show whether intracoronary abciximab administration leads to improved perfusion. The TIMI flow will be reported by the individual investigators

End point type	Secondary

End point timeframe:

immediately after percutaneous coronary intervention (PCI)

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	996	984		
Units: patients				
TIMI-flow 0	17	20		
TIMI-flow I	15	18		
TIMI-flow II	81	70		
TIMI-flow III	883	876		

Statistical analyses

Statistical analysis title	Secondary: TIMI-flow post PCI
Comparison groups	Abciximab i.c. v Abciximab i.v.

Number of subjects included in analysis	1980
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.74
Method	Chi-squared

Other pre-specified: GUSTO bleeding classification

End point title	GUSTO bleeding classification

End point description:

Safety endpoint: Bleeding until hospital discharge according to the GUSTO criteria: (a) severe or life-threatening: either intracranial hemorrhage or bleeding that causes hemodynamic compromise and requires intervention, (b) moderate: bleeding that requires blood transfusion, but does not result in hemodynamic compromise, or (c) mild: bleeding that does not meet the criteria for either severe or moderate bleeding.

End point type	Other pre-specified

End point timeframe:

up to discharge

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	986	998		
Units: patients				
Life-threatening or severe bleeding	26	19		
Moderate bleeding	27	25		
Minor bleeding	81	85		
No bleeding	852	869		

Statistical analyses

Statistical analysis title	Safety: GUSTO bleeding
Comparison groups	Abciximab i.c. v Abciximab i.v.
Number of subjects included in analysis	1984
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.72
Method	Chi-squared

Other pre-specified: Hemodynamic compromise during abciximab bolus administration

End point title	Hemodynamic compromise during abciximab bolus administration

End point description:

Safety endpoint: Hemodynamic compromise, defined as drop >15 mm Hg during abciximab bolus infusion; life-threatening arrhythmia (ventricular fibrillation and tachycardia) during abciximab bolus administration is assessed for safety

End point type	Other pre-specified

End point timeframe:

immediately after abciximab bolus administration

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	986	998		
Units: patients				
patients with event	1	6		
patients without event	985	992		

Statistical analyses

Statistical analysis title	Safety: hemodynamic compromise
Comparison groups	Abciximab i.c. v Abciximab i.v.
Number of subjects included in analysis	1984
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.06
Method	Chi-squared

Post-hoc: Life-threatening arrhythmia during abciximab bolus administration

End point title	Life-threatening arrhythmia during abciximab bolus administration

End point description:

End point type	Post-hoc

End point timeframe:

immediately after abciximab bolus administration

End point values	Abciximab i.c.	Abciximab i.v.		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	986	998		
Units: patient				
patients with event	17	21		
patients without event	969	977		

Statistical analyses

Statistical analysis title	Safety: Life-threatening arrhythmia
Comparison groups	Abciximab i.c. v Abciximab i.v.
Number of subjects included in analysis	1984
Analysis specification	Post-hoc
Analysis type	non-inferiority
P-value	= 0.25
Method	Chi-squared

Adverse events

Adverse events information	
Timeframe for reporting adverse events: until discharge from hospital	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	15.0
Reporting groups	
Reporting group title	Abciximab i.c.
Reporting group description: Abciximab bolus intracoronary	
Reporting group title	Abciximab i.v.
Reporting group description: Abciximab bolus intravenously	

Serious adverse events	Abciximab i.c.	Abciximab i.v.	
Total subjects affected by serious adverse events			
subjects affected / exposed	46 / 986 (4.67%)	45 / 998 (4.51%)	
number of deaths (all causes)	42	34	
number of deaths resulting from adverse events	16	18	
Vascular disorders			
Aortic dissection			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Artery dissection			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery occlusion			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemorrhage			

subjects affected / exposed	7 / 986 (0.71%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	7 / 8	1 / 1	
deaths causally related to treatment / all	2 / 3	0 / 0	
Hypertension			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemia			
subjects affected / exposed	1 / 986 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Peripheral ischaemia			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	2 / 986 (0.20%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vessel perforation			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Implantable defibrillator insertion			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Resuscitation			

subjects affected / exposed	1 / 986 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
General disorders and administration site conditions			
Mucosal haemorrhage			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ failure			
subjects affected / exposed	3 / 986 (0.30%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Sudden cardiac death			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemothorax			

subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	1 / 986 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Ventricular septal defect			
subjects affected / exposed	2 / 986 (0.20%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac disorders			
Acute myocardial infarction			

subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	1 / 986 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiac failure congestive			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac perforation			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac tamponade			
subjects affected / exposed	5 / 986 (0.51%)	7 / 998 (0.70%)	
occurrences causally related to treatment / all	5 / 5	7 / 7	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cardiogenic shock			
subjects affected / exposed	2 / 986 (0.20%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Cardiovascular insufficiency			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary artery occlusion			

subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dressler`s syndrome			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myocardial infarction			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Papillary muscle rupture	Additional description: Cardiac disorders		
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pericardial effusion			
subjects affected / exposed	2 / 986 (0.20%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial haemorrhage			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricle rupture			
subjects affected / exposed	1 / 986 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Ventricular fibrillation			

subjects affected / exposed	4 / 986 (0.41%)	7 / 998 (0.70%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 4	
Ventricular flutter			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	7 / 986 (0.71%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Nervous system disorders			
Brain injury			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	3 / 986 (0.30%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 986 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Disseminated intravascular			

coagulation			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Thrombocytopenia			
subjects affected / exposed	1 / 986 (0.10%)	4 / 998 (0.40%)	
occurrences causally related to treatment / all	0 / 1	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Acute abdomen			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 986 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	1 / 986 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Retroperitoneal haematoma			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			

Renal failure			
subjects affected / exposed	7 / 986 (0.71%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 6	0 / 0	
Renal failure acute			
subjects affected / exposed	1 / 986 (0.10%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Renal infarct			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Musculoskeletal and connective tissue disorders			
Compartment syndrome			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Infections and infestations			
Abdominal sepsis			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia			
subjects affected / exposed	4 / 986 (0.41%)	6 / 998 (0.60%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 3	0 / 4	
Puncture site infection			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	3 / 986 (0.30%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	

Septic encephalopathy			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 986 (0.00%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Staphylococcal sepsis			
subjects affected / exposed	0 / 986 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Lactic acidosis			
subjects affected / exposed	1 / 986 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Abciximab i.c.	Abciximab i.v.	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	157 / 986 (15.92%)	171 / 998 (17.13%)	
Vascular disorders			
Haematoma			
subjects affected / exposed	30 / 986 (3.04%)	36 / 998 (3.61%)	
occurrences (all)	31	36	
Haemorrhage			
subjects affected / exposed	43 / 986 (4.36%)	38 / 998 (3.81%)	
occurrences (all)	44	38	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	26 / 986 (2.64%)	33 / 998 (3.31%)	
occurrences (all)	28	33	
Ventricular tachycardia			

subjects affected / exposed occurrences (all)	29 / 986 (2.94%) 27	34 / 998 (3.41%) 33	
Surgical and medical procedures Percutaneous coronary intervention subjects affected / exposed occurrences (all)	31 / 986 (3.14%) 39	31 / 998 (3.11%) 35	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 October 2008	Three new sites were added , and one site was be closed due to a shortage in qualified personal. The University of Leipzig / Herzzentrum implemented another scientific side project, which will only be conducted at the Herzzentrum. The trial medication which was distributed by Lilly Germany from Gießen (central German storage place) until the amendment was be distributed from the European storage place of Lilly in Belgium after the amendment. Mmanufacturer, contents and labeling remained unchanged. Due to a relative high morbidity of the patients participating in this clinical trial, potential SAEs directly related to the underlying disease do not have be reported following an expedited reporting of SAEs as long as there is no suspicion of it being a SUSAR.
30 March 2009	Two new sites were added, change of PI at one trial site. To obtain comparabel and reliable data concerning the data from the 90 day follow-up examination, the working-instructions were specified with respect to acceptable source data and verification of potential findings. The recruitment period wasextended to three years. Change ofthe trial acronym to avoid mixing-up between different trials with the same substance and in similar indications.
11 May 2009	Use of Prasugrel as alternative to Clopidogrel. Change in the definition of patients considered as drop-out. Addition of a new trialsite and closure of one trial site. Addition of investigators to already participating trial sites.
19 November 2010	Closure of five trial sites due to insufficient capacity for proper trial conduct . Addition of capture of the time point of signature on the short form of the informed consent. Disposal of surplus or expired medication at the trial centres themselves insteadof re-shipment to Lilly. Increase of the patient number participating in the scientific MRT substudy to 1000. Additional investigarors in already participating trial sites.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/22357109

http://www.ncbi.nlm.nih.gov/pubmed/20362711

http://www.ncbi.nlm.nih.gov/pubmed/23850911