Clinical trial results:
A Randomized, Double-Blind, Active-Controlled Trial to Evaluate Intravenous and Oral PRT060128, a Selective and Reversible P2Y12-Receptor Inhibitor, vs. Clopidogrel, as a Novel Antiplatelet Therapy in Patients Undergoing Non-Urgent Percutaneous Coronary Interventions (INNOVATE-PCI)

Summary

EudraCT number	2008-001352-51
Trial protocol	DE AT
Global end of trial date	02 April 2010

Results information

Result version number	v1 (current)
This version publication date	18 December 2019
First version publication date	18 December 2019

Trial information

Trial identification

Sponsor protocol code	07-116

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Portola Pharmaceuticals, Inc.
Sponsor organisation address	270 East Grand Avenue, South San Francisco, United States, 94080
Public contact	Susanne Fors, Portola Pharmaceuticals, 001 650-246-7649, sfors@portola.com
Scientific contact	Susanne Fors, Portola Pharmaceuticals, 001 650-246-7649, sfors@portola.com

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	18 January 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 April 2010
Global end of trial reached?	Yes
Global end of trial date	02 April 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This was a Phase 2 study to evaluate the clinical efficacy, safety, and tolerability of intravenous (IV) and oral elinogrel (previously known as PRT060128) in patients undergoing non-urgent percutaneous coronary intervention (PCI).

Protection of trial subjects:

The protocol and informed consent form (ICF) for this study were reviewed and approved by an appropriate institutional review board (IRB)/research ethics board (REB)/independent ethics committee (IEC) before patients were randomized in the study. This study was designed, conducted, recorded, and reported in compliance with the principles set forth in the Declaration of Helsinki and with ICH guidelines. These guidelines are stated in U.S. federal regulations as well as in —Guidance for Good Clinical Practice, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 November 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 74
Country: Number of subjects enrolled	Austria: 28
Country: Number of subjects enrolled	Germany: 126
Country: Number of subjects enrolled	Canada: 132
Country: Number of subjects enrolled	United States: 292
Worldwide total number of subjects	652
EEA total number of subjects	228

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	416
From 65 to 84 years	236
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

After a diagnostic angiography, eligible patients scheduled for non-urgent PCI were randomized, study drug was initiated, and the PCI was performed.

Pre-assignment

Screening details:

1. The patient was scheduled to undergo non-urgent PCI.
2. The patient was between 18 and 75 years of age (inclusive) and willing to comply with the protocol

Period 1

Period 1 title	Patient Disposition (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	300/600mg Clopidogrel

Arm description:

Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)

Arm type	Active comparator
Investigational medicinal product name	Clopidogrel
Investigational medicinal product code	
Other name	Plavix
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Loading dose of 300mg or 600mg

Arm title	80mg IV + 50mg PO Elinogrel

Arm description:

Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)

Arm type	Experimental
Investigational medicinal product name	Elinogrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

80-120mg IV bolus administered prior to PCI, followed by twice daily doing of oral 50mg, 100mg or 150mg

Investigational medicinal product name	Elinogrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

80-120mg IV bolus administered prior to PCI, followed by twice daily doing of oral 50mg, 100mg or 150mg

Arm title	80mg IV + 100mg PO Elinogrel

Arm description:

Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)

Arm type	Experimental
Investigational medicinal product name	Elinogrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

80-120mg IV bolus administered prior to PCI, followed by twice daily dosing of oral 50mg, 100mg or 150mg

Investigational medicinal product name	Elinogrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

80-120mg IV bolus administered prior to PCI, followed by twice daily doing of oral 50mg, 100mg or 150mg

Arm title	80mg IV + 150mg PO Elinogrel

Arm description:

Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)

Arm type	Experimental
Investigational medicinal product name	Elinogrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

80-120 mg IV bolus administered prior to PCI, followed by twice daily doing of oral 50mg, 100mg or 150mg

Investigational medicinal product name	Elinogrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

80-120mg IV bolus administered prior to PCI, followed by twice daily dosing of oral 50mg, 100mg or 150mg

Arm title	120mg IV + 100mg PO Elinogrel

Arm description:

Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)

Arm type	Experimental
Investigational medicinal product name	Elinogrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

80-120mg IV bolus administered prior to PCI, followed by twice daily doing of oral 50mg, 100mg or 150mg

Investigational medicinal product name	Elinogrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

80-120mg IV bolus administered prior to PCI, followed by twice daily doing of oral 50mg, 100mg or 150mg

Arm title	120mg IV + 150mg PO Elinogrel

Arm description:

Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)

Arm type	Experimental
Investigational medicinal product name	Elinogrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

80-120mg IV bolus administered prior to PCI, followed by twice daily doing of oral 50mg, 100mg or 150mg

Investigational medicinal product name	Elinogrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

80-120mg IV bolus administered prior to PCI, followed by twice daily doing of oral 50mg, 100mg or 150mg

Number of subjects in period 1	300/600mg Clopidogrel	80mg IV + 50mg PO Elinogrel	80mg IV + 100mg PO Elinogrel
Started	212	26	50
Completed	154	21	32
Not completed	58	5	18
Adverse event, serious fatal	-	-	-
Physician decision	1	-	-
Consent withdrawn by subject	8	-	2
Adverse event, non-fatal	15	3	5

Visit prior to visit Time Window	24	2	6
not including Adverse Event	3	-	2
Lost to follow-up	-	-	-
Missing	3	-	2
Did Not Receive Treatment	4	-	1

Number of subjects in period 1	80mg IV + 150mg PO Elinogrel	120mg IV + 100mg PO Elinogrel	120mg IV + 150mg PO Elinogrel
Started	47	154	163
Completed	29	109	113
Not completed	18	45	50
Adverse event, serious fatal	-	1	-
Physician decision	-	1	2
Consent withdrawn by subject	-	4	6
Adverse event, non-fatal	6	8	11
Visit prior to visit Time Window	6	22	18
not including Adverse Event	1	3	6
Lost to follow-up	2	-	2
Missing	1	4	4
Did Not Receive Treatment	2	2	1

Baseline characteristics

Reporting groups	
Reporting group title	300/600mg Clopidogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	
Reporting group title	80mg IV + 50mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	
Reporting group title	80mg IV + 100mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	
Reporting group title	80mg IV + 150mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	
Reporting group title	120mg IV + 100mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	
Reporting group title	120mg IV + 150mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	

Reporting group values	300/600mg Clopidogrel	80mg IV + 50mg PO Elinogrel	80mg IV + 100mg PO Elinogrel
Number of subjects	212	26	50
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	60.9	61.4	60.6
standard deviation	± 8.53	± 8.84	± 8.45

Gender categorical Units: Subjects			
Female	50	6	9
Male	162	20	41

Reporting group values	80mg IV + 150mg PO Elinogrel	120mg IV + 100mg PO Elinogrel	120mg IV + 150mg PO Elinogrel
Number of subjects	47	154	163
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: years			
arithmetic mean	58.3	60.7	60.6
standard deviation	± 9.88	± 8.81	± 8.73
Gender categorical Units: Subjects			
Female	8	38	38
Male	39	116	125

Reporting group values	Total		
Number of subjects	652		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	149		
Male	503		

End points

End points reporting groups

Reporting group title	300/600mg Clopidogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	

Reporting group title	80mg IV + 50mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	

Reporting group title	80mg IV + 100mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	

Reporting group title	80mg IV + 150mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	

Reporting group title	120mg IV + 100mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	

Reporting group title	120mg IV + 150mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	

Subject analysis set title	Intention-to-Treat Population
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All patients randomized regardless of whether or not treatment was received	

Subject analysis set title	Efficacy Population
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
All patients who were randomized, received any study medication and the Index PCI	

Subject analysis set title	Safety Population
Subject analysis set type	Safety analysis
Subject analysis set description:	
All patients who were randomized and received any study medication	

Primary: Composite of death, myocardial infarction (MI), stroke, and urgent target vessel revascularization (UTVR)

End point title	Composite of death, myocardial infarction (MI), stroke, and urgent target vessel revascularization (UTVR)[1]
End point description:	
Clinical Efficacy Endpoint	

End point type	Primary

End point timeframe:

From initial treatment with study drug (Treatment) to 24 Hours or Discharge (whichever occurred first)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The study was an exploratory study and not powered for a statistical evaluation of endpoints. No hypotheses-driven statistical analyses were performed; data are presented using descriptive statistics.

End point values	300/600mg Clopidogrel	80mg IV + 50mg PO Elinogrel	80mg IV + 100mg PO Elinogrel	80mg IV + 150mg PO Elinogrel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	208	26	48	44
Units: Number of Participants	10	3	5	1

End point values	120mg IV + 100mg PO Elinogrel	120mg IV + 150mg PO Elinogrel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	152	160		
Units: Number of Participants	11	14		

Statistical analyses

No statistical analyses for this end point

Secondary: Composite of death, MI, stroke, UTVR, and stent thrombosis

End point title	Composite of death, MI, stroke, UTVR, and stent thrombosis

End point description:

Clinical Efficacy Endpoint

End point type	Secondary

End point timeframe:

From initial treatment with study drug (Treatment) to 24 Hours or Discharge (whichever occurred first)

End point values	300/600mg Clopidogrel	80mg IV + 50mg PO Elinogrel	80mg IV + 100mg PO Elinogrel	80mg IV + 150mg PO Elinogrel
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	208	26	48	44
Units: Number of Participants	10	3	5	1

End point values	120mg IV + 100mg PO Elinogrel	120mg IV + 150mg PO Elinogrel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	152	160		
Units: Number of Participants	11	14		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From randomization to 7 days after the last received dose

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	13

Reporting groups

Reporting group title	300/600mg Clopidogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	
Reporting group title	80mg IV + 50mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	
Reporting group title	80mg IV + 100mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	
Reporting group title	80mg IV + 150mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	
Reporting group title	120mg IV + 100mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	
Reporting group title	120mg IV + 150mg PO Elinogrel
Reporting group description:	
Intention-to-Treat Population (all patients randomized regardless of whether or not treatment was received)	

Serious adverse events	300/600mg Clopidogrel	80mg IV + 50mg PO Elinogrel	80mg IV + 100mg PO Elinogrel
Total subjects affected by serious adverse events			
subjects affected / exposed	23 / 208 (11.06%)	4 / 26 (15.38%)	8 / 49 (16.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer stage II			

subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma stage I			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery occlusion			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	4 / 208 (1.92%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Thrombosis in device			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	2 / 49 (4.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Facial bones fracture			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional overdose			

subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural myocardial infarction			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	2 / 208 (0.96%)	1 / 26 (3.85%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	2 / 208 (0.96%)	1 / 26 (3.85%)	2 / 49 (4.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 208 (0.00%)	1 / 26 (3.85%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			

subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery perforation			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus arrest			

subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystles			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient global amnesia			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Groin pain			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal pain			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 208 (0.00%)	1 / 26 (3.85%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 208 (0.00%)	1 / 26 (3.85%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hyponatraemia			
subjects affected / exposed	0 / 208 (0.00%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	80mg IV + 150mg PO Elinogrel	120mg IV + 100mg PO Elinogrel	120mg IV + 150mg PO Elinogrel
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 47 (6.38%)	22 / 152 (14.47%)	23 / 160 (14.38%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer stage II			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma stage I			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery occlusion			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			

subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	2 / 160 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis in device			
subjects affected / exposed	1 / 47 (2.13%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	2 / 160 (1.25%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			

subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	3 / 160 (1.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Facial bones fracture			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional overdose			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural myocardial infarction			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Angina pectoris			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	3 / 160 (1.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	4 / 160 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 47 (2.13%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery perforation			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			

subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 47 (2.13%)	3 / 152 (1.97%)	4 / 160 (2.50%)
occurrences causally related to treatment / all	1 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus arrest			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystles			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			

subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 47 (2.13%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient global amnesia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			

Cholelithiasis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Groin pain			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	2 / 160 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Subcutaneous abscess			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 152 (0.66%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	300/600mg Clopidogrel	80mg IV + 50mg PO Elinogrel	80mg IV + 100mg PO Elinogrel
Total subjects affected by non-serious adverse events			
subjects affected / exposed	122 / 208 (58.65%)	17 / 26 (65.38%)	34 / 49 (69.39%)
Investigations			
Liver function test abnormal			
subjects affected / exposed	1 / 208 (0.48%)	0 / 26 (0.00%)	2 / 49 (4.08%)
occurrences (all)	1	0	2
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	12 / 208 (5.77%)	2 / 26 (7.69%)	3 / 49 (6.12%)
occurrences (all)	20	2	3
Vascular disorders			
Haematoma			
subjects affected / exposed	7 / 208 (3.37%)	1 / 26 (3.85%)	1 / 49 (2.04%)
occurrences (all)	8	1	1

Hypertension			
subjects affected / exposed	4 / 208 (1.92%)	0 / 26 (0.00%)	0 / 49 (0.00%)
occurrences (all)	4	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	15 / 208 (7.21%)	1 / 26 (3.85%)	5 / 49 (10.20%)
occurrences (all)	17	1	5
Nervous system disorders			
Dizziness			
subjects affected / exposed	7 / 208 (3.37%)	1 / 26 (3.85%)	0 / 49 (0.00%)
occurrences (all)	8	1	0
Headache			
subjects affected / exposed	8 / 208 (3.85%)	1 / 26 (3.85%)	4 / 49 (8.16%)
occurrences (all)	8	1	5
General disorders and administration site conditions			
Catheter site haematoma			
subjects affected / exposed	5 / 208 (2.40%)	1 / 26 (3.85%)	3 / 49 (6.12%)
occurrences (all)	6	1	3
Catheter site haemorrhage			
subjects affected / exposed	4 / 208 (1.92%)	5 / 26 (19.23%)	3 / 49 (6.12%)
occurrences (all)	4	5	3
Fatigue			
subjects affected / exposed	8 / 208 (3.85%)	0 / 26 (0.00%)	3 / 49 (6.12%)
occurrences (all)	8	0	3
Non-cardiac chest pain			
subjects affected / exposed	7 / 208 (3.37%)	2 / 26 (7.69%)	0 / 49 (0.00%)
occurrences (all)	8	2	0
Chest discomfort			
subjects affected / exposed	3 / 208 (1.44%)	3 / 26 (11.54%)	4 / 49 (8.16%)
occurrences (all)	3	3	4
Chest pain			
subjects affected / exposed	4 / 208 (1.92%)	0 / 26 (0.00%)	4 / 49 (8.16%)
occurrences (all)	4	0	4
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	4 / 208 (1.92%)	2 / 26 (7.69%)	0 / 49 (0.00%)
occurrences (all)	4	2	0
Gingival bleeding			
subjects affected / exposed	2 / 208 (0.96%)	2 / 26 (7.69%)	1 / 49 (2.04%)
occurrences (all)	2	3	1
Nausea			
subjects affected / exposed	9 / 208 (4.33%)	1 / 26 (3.85%)	1 / 49 (2.04%)
occurrences (all)	11	1	2
Vomiting			
subjects affected / exposed	4 / 208 (1.92%)	2 / 26 (7.69%)	1 / 49 (2.04%)
occurrences (all)	4	2	1
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	8 / 208 (3.85%)	1 / 26 (3.85%)	9 / 49 (18.37%)
occurrences (all)	8	1	11
Epistaxis			
subjects affected / exposed	6 / 208 (2.88%)	1 / 26 (3.85%)	1 / 49 (2.04%)
occurrences (all)	7	1	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 208 (0.48%)	2 / 26 (7.69%)	1 / 49 (2.04%)
occurrences (all)	1	2	1
Back pain			
subjects affected / exposed	13 / 208 (6.25%)	1 / 26 (3.85%)	3 / 49 (6.12%)
occurrences (all)	14	1	3

Non-serious adverse events	80mg IV + 150mg PO Elinogrel	120mg IV + 100mg PO Elinogrel	120mg IV + 150mg PO Elinogrel
Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 47 (72.34%)	91 / 152 (59.87%)	107 / 160 (66.88%)
Investigations			
Liver function test abnormal			
subjects affected / exposed	3 / 47 (6.38%)	3 / 152 (1.97%)	3 / 160 (1.88%)
occurrences (all)	3	3	3
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	2 / 47 (4.26%)	6 / 152 (3.95%)	7 / 160 (4.38%)
occurrences (all)	2	6	10
Vascular disorders			
Haematoma			
subjects affected / exposed	3 / 47 (6.38%)	6 / 152 (3.95%)	9 / 160 (5.63%)
occurrences (all)	3	7	9
Hypertension			
subjects affected / exposed	3 / 47 (6.38%)	1 / 152 (0.66%)	3 / 160 (1.88%)
occurrences (all)	3	1	4
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	2 / 47 (4.26%)	6 / 152 (3.95%)	5 / 160 (3.13%)
occurrences (all)	2	6	6
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 47 (4.26%)	5 / 152 (3.29%)	8 / 160 (5.00%)
occurrences (all)	2	5	8
Headache			
subjects affected / exposed	4 / 47 (8.51%)	3 / 152 (1.97%)	8 / 160 (5.00%)
occurrences (all)	4	3	9
General disorders and administration site conditions			
Catheter site haematoma			
subjects affected / exposed	2 / 47 (4.26%)	5 / 152 (3.29%)	14 / 160 (8.75%)
occurrences (all)	2	5	14
Catheter site haemorrhage			
subjects affected / exposed	1 / 47 (2.13%)	6 / 152 (3.95%)	2 / 160 (1.25%)
occurrences (all)	1	6	2
Fatigue			
subjects affected / exposed	1 / 47 (2.13%)	2 / 152 (1.32%)	4 / 160 (2.50%)
occurrences (all)	1	2	4
Non-cardiac chest pain			
subjects affected / exposed	2 / 47 (4.26%)	7 / 152 (4.61%)	5 / 160 (3.13%)
occurrences (all)	2	8	5
Chest discomfort			

subjects affected / exposed	3 / 47 (6.38%)	1 / 152 (0.66%)	3 / 160 (1.88%)
occurrences (all)	3	1	3
Chest pain			
subjects affected / exposed	0 / 47 (0.00%)	6 / 152 (3.95%)	7 / 160 (4.38%)
occurrences (all)	0	6	7
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 47 (6.38%)	0 / 152 (0.00%)	3 / 160 (1.88%)
occurrences (all)	4	0	4
Gingival bleeding			
subjects affected / exposed	0 / 47 (0.00%)	0 / 152 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 47 (2.13%)	5 / 152 (3.29%)	8 / 160 (5.00%)
occurrences (all)	1	5	9
Vomiting			
subjects affected / exposed	1 / 47 (2.13%)	1 / 152 (0.66%)	2 / 160 (1.25%)
occurrences (all)	1	1	2
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 47 (6.38%)	16 / 152 (10.53%)	22 / 160 (13.75%)
occurrences (all)	3	19	23
Epistaxis			
subjects affected / exposed	2 / 47 (4.26%)	12 / 152 (7.89%)	8 / 160 (5.00%)
occurrences (all)	2	14	9
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 152 (0.00%)	1 / 160 (0.63%)
occurrences (all)	1	0	1
Back pain			
subjects affected / exposed	0 / 47 (0.00%)	7 / 152 (4.61%)	3 / 160 (1.88%)
occurrences (all)	0	7	3

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 April 2009	1. For patients requiring repeat (elective or urgent) revascularization during the study, reloading the patient with elinogrel/placebo IV bolus (Kit A ±X) and the clopidogrel/placebo loading dose (Kit C) should be performed. 2. To ensure consistent antiplatelet coverage during the transition to open-label therapy at the end of study participation, a regimen for clopidogrel reloading was recommended. 3. The timing of the second oral dose of elinogrel (Kit B) was updated to ensure that patients receive their second dose in the evening of their index PCI. 4. The treatment period for chronic oral dosing was extended from 60 days to 120 days; patients who are currently active on the study at the time of approval of the amendment will have the option to sign a new consent form in order to participate for the extended period of 120 days. Corresponding Day 120 endpoints were added to assess efficacy and safety. 5. An administrative interim analysis after all patients have completed the first 60 days of treatment was added. 6. Inclusion criterion #3 was modified to require two forms of contraception, one of which must consist of oral or injected contraceptives, transdermal hormone patch, subdermal implants, IUD with hormones or copper, or surgical sterilization. 7. Exclusion criterion #11 regarding administration of thrombolytic agents, fondaparinux, or oral anticoagulants (e.g., warfarin) within the 7 days prior to PCI was modified to also exclude patients with a requirement for chronic oral anticoagulation. 8. At the recommendation of the DSMC, the 50 mg dose level was dropped from randomization on April 8, 2009.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported