A Clinical Trial Comparing Cangrelor to Clopidogrel Standard Therapy in Subjects Who Require Percutaneous Coronary Intervention (PCI) (CHAMPION PHOENIX) (CHAMPION)

ClinicalTrials.gov Identifier: NCT01156571

Recruitment Status : Completed
First Posted : July 5, 2010
Results First Posted : June 18, 2013
Last Update Posted : February 4, 2014

Sponsor:

The Medicines Company

Information provided by (Responsible Party):

The Medicines Company

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions	Atherosclerosis Percutaneous Coronary Intervention Acute Coronary Syndrome
Interventions	Drug: cangrelor P2Y12 (platelet) inhibitor Drug: Clopidogrel - 300 or 600 mg (study arm) Drug: Clopidogrel 600 mg post cangrelor
Enrollment	11145

Participant Flow

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Recruitment Details	Date first patient enrolled: 30 Sep 2010 Date last patient completed: 14 Nov 2012 This trial enrolled the full spectrum of patients who required PCI (SA, NSTE-ACS, STEMI). Randomization occurred after confirmation of need for PCI (after diagnostic angiogram in all cases, except for STEMI patients). Patients were followed through 30-days.
Pre-assignment Details	Due to the nature of the disease, STEMI patients were permitted to be randomized upon ECG confirmation and prior to confirmation of need for PCI (prior to diagnostic angiography). Therefore in some cases, STEMI patients did not require PCI and therefore did not receive all study drug.

Arm/Group Title	Cangrelor Treatment Arm	Clopidogrel Treatment Arm
▼ Arm/Group Description	Cangrelor was administered as a 30 µg/kg bolus followed by a 4.0 µg/kg/min cangrelor IV infusion for a minimum of 2 hours or until conclusion of the index procedure, whichever is longer. At the discretion of the treating physician, the infusion could be continued for a total duration of 4 hours. Immediately after discontinuation of infusion, an oral transition dose of clopidogrel 600 mg was administered. Patients also received oral placebo capsules, administered as soon as possible following randomization at investigator discretion. These capsules were designed to match the clopidogrel 600 mg or 300 mg loading dose.	Oral clopidogrel was administered as soon as possible following randomization at investigator discretion at a loading dose of either 600 mg or 300 mg as specified by the investigator. Patients in the clopidogrel treatment arm received IV placebo for 2 hours or end of the PCI procedure, whichever was longer. At the discretion of the treating physician, the infusion could be continued for a total duration of 4 hours. At the end of IV placebo infusion, patients were given oral placebo capsules matching the oral clopidogrel transition dose.
Period Title: **Overall Study**		
Started	5581 [1]	5564 [1]
Completed	5564 [2]	5545 [2]
Not Completed	17	19

[1] ITT: defined as all patients randomized.

[2] Completed = ITT patients who completed scheduled visits or developed a primary endpoint event

Baseline Characteristics

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Arm/Group Title	Cangrelor Treatment Arm	Clopidogrel Treatment Arm	Total

Arm/Group Title	Cangrelor Treatment Arm	Clopidogrel Treatment Arm	Total
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Overall Number of Baseline Participants	5581	5564	11145
▼ Baseline Analysis Population Description	ITT population		
Age, Categorical			

Age, Categorical Measure Type: Count of Participants Unit of measure: Participants							
	Number Analyzed	5581 participants		5564 participants		11145 participants	
	<=18 years	0	0.0%	0	0.0%	0	0.0%
	Between 18 and 65 years	2892	51.8%	2902	52.2%	5794	52.0%
	>=65 years	2689	48.2%	2662	47.8%	5351	48.0%
Age, Continuous Mean (Standard Deviation) Unit of measure: Years							
	Number Analyzed	5581 participants		5564 participants		11145 participants	
		64.0 (11.0)		63.8 (11.0)		63.9 (11.0)	
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants							
	Number	5581 participants		5564 participants		11145 participants	

	Analyzed						
	Female	1599	28.7%	1522	27.4%	3121	28.0%
	Male	3982	71.3%	4042	72.6%	8024	72.0%
Region of Enrollment Measure Type: Number Unit of measure: Participants	Number Analyzed	5581 participants		5564 participants		11145 participants	
United States		2099		2089		4188	
Austria		302		300		602	
Brazil		78		80		158	
Bulgaria		169		167		336	
Czech Republic		814		816		1630	
Georgia		744		741		1485	
Germany		243		251		494	
Italy		311		310		621	
New Zealand		22		23		45	
Poland		352		350		702	
Russian Federation		296		286		582	
Thailand		151		151		302	

Outcome Measures

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1. Primary Outcome

Title	The Composite Incidence of All-cause Mortality, Myocardial Infarction (MI), Ischemia-driven Revascularization

Title	The Composite Incidence of All-cause Mortality, Myocardial Infarction (MI), Ischemia-driven Revascularization (IDR) and Stent Thrombosis (ST)
▼ Description	Clinical Events Committee (CEC)-adjudicated results (modified intent-to-treat [mITT] population)
Time Frame	48 hours after randomization

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	Cangrelor Treatment Arm	Clopidogrel Treatment Arm
▼ Arm/Group Description:	[Not Specified]	[Not Specified]
Overall Number of Participants Analyzed	5470	5469
Measure Type: Number Unit of Measure: participants		
	257	322

2. Secondary Outcome

Title	Individual Incidence of Stent Thrombosis (ST), Death, Myocardial Infarction (MI) and Ischemia-driven Revascularization (IDR)
▼ Description	CEC-adjudicated results (mITT population)
Time Frame	48 hours after randomization

▼ Outcome Measure Data

▼ Analysis Population Description

[Not Specified]

Arm/Group Title	Cangrelor Treatment Arm	Clopidogrel Treatment Arm
▼ Arm/Group Description:	[Not Specified]	[Not Specified]
Overall Number of Participants Analyzed	5470	5469
Measure Type: Number Unit of Measure: participants		
Stent Thrombosis	46	74
Death	18	18
MI (myocardial infarction)	207	255
IDR (ischemia-driven revascularization)	28	38

3. Secondary Outcome

Title	Incidence of Major/Minor Non-coronary Artery Bypass Graft (CABG)-Related Hemorrhage by Clinical Relevant Criteria - GUSTO Severe/Life-threatening, Moderate and Mild
▼ Description	GUSTO = Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Coronary Arteries trial
Time Frame	48 hours after randomization

▼ Outcome Measure Data

▼ Analysis Population Description

[Not Specified]

Arm/Group Title	Cangrelor Treatment Arm	Clopidogrel Treatment Arm
▼ Arm/Group Description:	[Not Specified]	[Not Specified]
Overall Number of Participants Analyzed	5529	5527
Measure Type: Number Unit of Measure: participants		
GUSTO severe/life threatening	9	6
GUSTO moderate	22	13
GUSTO severe or moderate	31	19
TIMI major	5	5
TIMI minor	9	3
TIMI major or minor	14	8
Any blood transfusion	25	16

Adverse Events

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Time Frame	AEs and SAEs were collected from the time of randomization until 48 hours after randomization. If there was a delay between randomization and study drug initiation, AEs were collected from randomization through 48 hours after study drug initiation.

Adverse Event Reporting Description	[Not Specified]

Arm/Group Title	Cangrelor Treatment Arm	Clopidogrel Treatment Arm
▼ Arm/Group Description	[Not Specified]	[Not Specified]

All-Cause Mortality

	Cangrelor Treatment Arm	Clopidogrel Treatment Arm
	Affected / at Risk (%)	Affected / at Risk (%)
Total	--/--	--/--

▼ Serious Adverse Events

	Cangrelor Treatment Arm	Clopidogrel Treatment Arm
	Affected / at Risk (%)	Affected / at Risk (%)
Total	122/5529 (2.21%)	105/5527 (1.90%)
Blood and lymphatic system disorders		
Anaemia	1/5529 (0.02%)	0/5527 (0.00%)
Hypersplenism	0/5529 (0.00%)	1/5527 (0.02%)
Pancytopenia	0/5529 (0.00%)	1/5527 (0.02%)
Cardiac disorders		
acute coronary syndrome	1/5529 (0.02%)	0/5527 (0.00%)
acute myocardial infarction	2/5529 (0.04%)	3/5527 (0.05%)
angina pectoris	1/5529 (0.02%)	1/5527 (0.02%)
angina unstable	2/5529 (0.04%)	1/5527 (0.02%)
Arteriospasm coronary	1/5529 (0.02%)	0/5527 (0.00%)
atrial fibrillation	2/5529 (0.04%)	2/5527 (0.04%)
atrioventricular block complete	3/5529 (0.05%)	3/5527 (0.05%)

bradycardia	1/5529 (0.02%)	1/5527 (0.02%)
cardiac arrest	5/5529 (0.09%)	8/5527 (0.14%)
cardiac failure	1/5529 (0.02%)	3/5527 (0.05%)
cardiac failure acute	1/5529 (0.02%)	0/5527 (0.00%)
cardiac failure congestive	3/5529 (0.05%)	3/5527 (0.05%)
cardiac tamponade	1/5529 (0.02%)	0/5527 (0.00%)
cardio-respiratory arrest	3/5529 (0.05%)	1/5527 (0.02%)
cardiogenic shock	12/5529 (0.22%)	6/5527 (0.11%)
coronary artery disease	0/5529 (0.00%)	1/5527 (0.02%)
coronary artery dissection	9/5529 (0.16%)	6/5527 (0.11%)
coronary artery occlusion	0/5529 (0.00%)	4/5527 (0.07%)
coronary artery performation	3/5529 (0.05%)	3/5527 (0.05%)
Interventricluar septum rupture	2/5529 (0.04%)	0/5527 (0.00%)
myocardial infarction	2/5529 (0.04%)	1/5527 (0.02%)
mycardial rupture	0/5529 (0.00%)	3/5527 (0.05%)
nodal arrhythmia	1/5529 (0.02%)	1/5527 (0.02%)
percarditis	0/5529 (0.00%)	1/5527 (0.02%)
sick sinus syndrome	1/5529 (0.02%)	1/5527 (0.02%)
sinus arrest	1/5529 (0.02%)	0/5527 (0.00%)
ventricular rupture	1/5529 (0.02%)	0/5527 (0.00%)
ventricular asystole	0/5529 (0.00%)	1/5527 (0.02%)
ventricular fibrillation	6/5529 (0.11%)	7/5527 (0.13%)
ventricluar tachycardia	5/5529 (0.09%)	3/5527 (0.05%)
Gastrointestinal disorders		
gastroesophageal reflux disease	0/5529 (0.00%)	1/5527 (0.02%)
General disorders		
chest discomfort	1/5529 (0.02%)	0/5527 (0.00%)

chest pain	5/5529 (0.09%)	2/5527 (0.04%)
non-cardiac chest pain	2/5529 (0.04%)	0/5527 (0.00%)
pyrexia	0/5529 (0.00%)	1/5527 (0.02%)
thrombosis in device	3/5529 (0.05%)	3/5527 (0.05%)
Hepatobiliary disorders		
hepatic cirrhosis	0/5529 (0.00%)	1/5527 (0.02%)
Immune system disorders		
anaphylactic reaction	2/5529 (0.04%)	0/5527 (0.00%)
anaphylactic shock	1/5529 (0.02%)	0/5527 (0.00%)
hypersensitivity	0/5529 (0.00%)	2/5527 (0.04%)
Infections and infestations		
bronchitis	1/5529 (0.02%)	0/5527 (0.00%)
pneumonia	1/5529 (0.02%)	1/5527 (0.02%)
septic shock	1/5529 (0.02%)	0/5527 (0.00%)
small intestine gangrene	1/5529 (0.02%)	0/5527 (0.00%)
urinary tract infection	0/5529 (0.00%)	1/5527 (0.02%)
Injury, poisoning and procedural complications		
cardiac procedure complication	0/5529 (0.00%)	1/5527 (0.02%)
fall	0/5529 (0.00%)	1/5527 (0.02%)
head injury	0/5529 (0.00%)	1/5527 (0.02%)
medication error	1/5529 (0.02%)	0/5527 (0.00%)
postoperative ileus	1/5529 (0.02%)	0/5527 (0.00%)
subdural haematoma	0/5529 (0.00%)	1/5527 (0.02%)
vascular pseudoaneurysm	1/5529 (0.02%)	0/5527 (0.00%)
Investigations		
blood creatinine increased	3/5529 (0.05%)	1/5527 (0.02%)

electrocardiogram ST segment elevation	0/5529 (0.00%)	1/5527 (0.02%)
troponin increased	1/5529 (0.02%)	2/5527 (0.04%)
Metabolism and nutrition disorders		
diabetes mellitus	1/5529 (0.02%)	0/5527 (0.00%)
fluid overload	0/5529 (0.00%)	1/5527 (0.02%)
Musculoskeletal and connective tissue disorders		
compartment syndrome	1/5529 (0.02%)	0/5527 (0.00%)
neck pain	0/5529 (0.00%)	1/5527 (0.02%)
Nervous system disorders		
cerebrovascular accident	0/5529 (0.00%)	2/5527 (0.04%)
embolic cerebral infarction	0/5529 (0.00%)	1/5527 (0.02%)
ischaemic stroke	2/5529 (0.04%)	1/5527 (0.02%)
lethargy	0/5529 (0.00%)	1/5527 (0.02%)
migraine	1/5529 (0.02%)	0/5527 (0.00%)
presyncope	1/5529 (0.02%)	3/5527 (0.05%)
transient ischaemic attack	1/5529 (0.02%)	1/5527 (0.02%)
Psychiatric disorders		
delirium	1/5529 (0.02%)	1/5527 (0.02%)
mental status changes	0/5529 (0.00%)	3/5527 (0.05%)
Renal and urinary disorders		
nephrolithiasis	1/5529 (0.02%)	0/5527 (0.00%)
nephropathy toxic	1/5529 (0.02%)	2/5527 (0.04%)
renal failure	2/5529 (0.04%)	1/5527 (0.02%)
renal failure acute	2/5529 (0.04%)	2/5527 (0.04%)
renal impairment	1/5529 (0.02%)	0/5527 (0.00%)
Respiratory, thoracic and mediastinal		

disorders		
aspiration	1/5529 (0.02%)	0/5527 (0.00%)
chronic obstructive pulmonary disease	0/5529 (0.00%)	1/5527 (0.02%)
dyspnoea	1/5529 (0.02%)	0/5527 (0.00%)
dyspnoea exertional	1/5529 (0.02%)	0/5527 (0.00%)
pulmonary embolism	2/5529 (0.04%)	0/5527 (0.00%)
pulmonary oedema	6/5529 (0.11%)	3/5527 (0.05%)
respiratory failure	2/5529 (0.04%)	0/5527 (0.00%)
Vascular disorders		
aortic dissection	1/5529 (0.02%)	0/5527 (0.00%)
arterial rupture	2/5529 (0.04%)	2/5527 (0.04%)
circulatory collapse	0/5529 (0.00%)	1/5527 (0.02%)
deep vein thrombosis	1/5529 (0.02%)	0/5527 (0.00%)
hypertension	0/5529 (0.00%)	1/5527 (0.02%)
hypotension	7/5529 (0.13%)	3/5527 (0.05%)

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%

	Cangrelor Treatment Arm	Clopidogrel Treatment Arm
	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/5529 (0.00%)	0/5527 (0.00%)

Limitations and Caveats

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[Not Specified]

More Information

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Certain Agreements

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

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

In general, PI communications regarding trial results are prohibited until after the communication and publication of the multi-center results by Sponsor, but no more than 12 months after conclusion of the trial at all sites.

PI must submit results communications to sponsor for review at least 45 days prior to submission for publication and Sponsor may embargo such communications for a period that is less than or equal to 135 days solely to seek appropriate patent protection.

Results Point of Contact

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