ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 08/30/2011

ClinicalTrials.gov ID: NCT00642811

Study Identification

Unique Protocol ID:	D5130C00030
Brief Title:	A Study of the Antiplatelet Effects Comparing Ticagrelor (Ticag. - AZD6140) With Clopidogrel (Clop.) Responder and Non-responders (RESPOND)
Official Title:	A Randomised, Double-Blind, Outpatient, Crossover Study of the Anti-platelet Effects of Ticagrelor Compared With Clopidogrel in Patients With Stable Coronary Artery Disease Previously Identified as Clopidogrel Non-responders or Responders [RESPOND]
Secondary IDs:	

Study Status

Record Verification:	August 2011
Overall Status:	Completed
Study Start:	May 2008
Primary Completion:	March 2009 [Actual]
Study Completion:	March 2009 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 65,808 Serial Number: 225 Has Expanded Access? No
Review Board:	Approval Status: Approved Approval Number: 1422 Board Name: LifeBridge Health, Inc. Institutional Review Board Board Affiliation: US Food & Drug Administration Phone: +1- 410-601-9021 Email: plohinski@lifebridgehealth.org
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	The purpose of this study is to see how Ticagrelor, a new oral reversible anti-platelet medication, affects platelets. Anti-platelet agents are medications that block the formation of blood clots by preventing the clumping of platelets. Blood clots prevent us from bleeding, but when they form inside the arteries their formation is linked to a risk of medical problems such as heart attack and stroke. This study investigated the effect of Ticagrelor on inhibition of platelet aggregation compared with clopidogrel in patients previously identified as non-responsive to clopidogrel.
Detailed Description:	

Conditions

Conditions:	Stable Coronary Artery Disease
Keywords:	coronary artery disease (CAD) heart attack stable angina

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Crossover Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Pharmacodynamics Study
Enrollment:	98 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Aspirin + Ticagrelor	Drug: Ticagrelor Tablets, Oral, 90 mg; 180 mg loading dose followed by 90 mg twice daily for 2 weeks Drug: Aspirin Tablets, Oral, 75 mg to 100 mg once daily. Aspirin obtained locally by the investigator, according to local practice. The dose remained constant throughout the study
Active Comparator: 2 Aspirin + Clopidogrel	Drug: Clopidogrel (over encapsulated) capsule, Oral, 75 mg; 600 mg loading dose followed by 75 mg once daily for 2 weeks Other Names: • Plavix Drug: Aspirin Tablets, Oral, 75 mg to 100 mg once daily. Aspirin obtained locally by the investigator, according to local practice. The dose remained constant throughout the study

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Patients with documented stable Coronary Artery Disease (CAD) (stable angina, previous MI history, previous history of revascularization)
- Females of child bearing potential must have a negative pregnancy test prior to receiving study drug and be willing to use a hormonal contraceptive in addition to double barrier contraception

Exclusion Criteria:

- History of Acute Coronary Syndromes within 12 months of screening or need for revascularization (angioplasty or coronary artery bypass graft (CABG))
- Any acute or chronic unstable condition in the past 30 days
- Have increased bleeding risk, eg, recent gastrointestinal bleed, uncontrolled high blood pressure, low platelet count, recent major trauma
- History of intolerance or allergy to aspirin or clopidogrel

Contacts/Locations

Study Officials: Jay Horrow, MD
Study Director
AstraZeneca

Paul Gurbel, md
Study Principal Investigator
Platelet & Thrombosis Research, LLC

Locations: United States, Maryland
Research Site
Baltimore, Maryland, United States

United States, Ohio
Research Site
Cincinnati, Ohio, United States

Denmark
Research Site

Esbjerg, Denmark

Research Site
Aalborg, Denmark

Research Site
Arhus, Denmark

United Kingdom
Research Site
Sheffield, United Kingdom

Canada, Ontario
Research Site
Hamilton, Ontario, Canada

United States, Florida
Research Site
Ormond Beach, Florida, United States

United States, Arkansas
Research Site
Jonesboro, Arkansas, United States

Canada
Research Site
Lachine, Canada

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Reporting Groups

	Description
Clopidogrel Non-responders - Clopidogrel to Ticagrelor	Non-responder definition: patients with an absolute difference of less than or equal to 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist. Clopidogrel 600 mg loading dose followed by 75 mg once daily (od) for 2 weeks; switch to ticagrelor 180 mg loading dose followed by 90 mg twice daily (bd) for 2 weeks.
Clopidogrel Non-responders - Ticagrelor to Clopidogrel	Non-responder definition: patients with an absolute difference of less than or equal to 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist. Ticagrelor 180 mg loading dose followed by 90 mg twice daily (bd) for 2 weeks; switch to clopidogrel 600 mg loading dose followed by 75 mg once daily (od) for 2 weeks.
Clopidogrel Responders - Clopidogrel to Clopidogrel	Responder definition: patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist. Clopidogrel 600 mg loading dose followed by 75 mg once daily (od) for 2 weeks; stay on clopidogrel 75 mg once daily (od) for 2 weeks
Clopidogrel Responders - Clopidogrel to Ticagrelor	Responder definition: patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist. Clopidogrel 600 mg loading dose followed by 75 mg once daily (od) for 2 weeks; switch to ticagrelor 180 mg loading dose followed by 90 mg twice daily (bd) for 2 weeks.
Clopidogrel Responders - Ticagrelor to Clopidogrel	Responder definition: patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist. Ticagrelor 180 mg loading dose followed by 90 mg twice daily (bd) for 2 weeks; switch to clopidogrel 600 mg loading dose followed by 75 mg once daily (od) for 2 weeks.
Clopidogrel Responders - Ticagrelor to Ticagrelor	Responder definition: patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist. Ticagrelor 180 mg loading dose followed by 90 mg twice daily (bd) for 2 weeks; stay on ticagrelor 90 mg twice daily (bd) for 2 weeks.

Overall Study

	Clopidogrel Non-responders - Clopidogrel to Ticagrelor	Clopidogrel Non-responders - Ticagrelor to Clopidogrel	Clopidogrel Responders - Clopidogrel to Clopidogrel	Clopidogrel Responders - Clopidogrel to Ticagrelor	Clopidogrel Responders - Ticagrelor to Clopidogrel	Clopidogrel Responders - Ticagrelor to Ticagrelor
Started	20	21	13	16	14	14

	Clopidogrel Non-responders - Clopidogrel to Ticagrelor	Clopidogrel Non-responders - Ticagrelor to Clopidogrel	Clopidogrel Responders - Clopidogrel to Clopidogrel	Clopidogrel Responders - Clopidogrel to Ticagrelor	Clopidogrel Responders - Ticagrelor to Clopidogrel	Clopidogrel Responders - Ticagrelor to Ticagrelor
Completed	17	17	13	15	13	13
Not Completed	3	4	0	1	1	1
Adverse Event	2	3	0	0	0	1
Developement of discontinuation criteria	0	0	0	0	1	0
Severe Non-compliance to protocol	1	0	0	0	0	0
Other	0	1	0	1	0	0

Baseline Characteristics

Reporting Groups

	Description
Clopidogrel Non-responders - Clopidogrel to Ticagrelor	Non-responder definition: patients with an absolute difference of less than or equal to 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist
Clopidogrel Non-responders - Ticagrelor to Clopidogrel	Non-responder definition: patients with an absolute difference of less than or equal to 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist
Clopidogrel Responders - Clopidogrel to Clopidogrel	Responder definition: patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist
Clopidogrel Responders - Clopidogrel to Ticagrelor	Responder definition: patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist
Clopidogrel Responders - Ticagrelor to Clopidogrel	Responder definition: patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist
Clopidogrel Responders - Ticagrelor to Ticagrelor	Responder definition: patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist

Baseline Measures

	Clopidogrel Non-responders - Clopidogrel to Ticagrelor	Clopidogrel Non-responders - Ticagrelor to Clopidogrel	Clopidogrel Responders - Clopidogrel to Clopidogrel	Clopidogrel Responders - Clopidogrel to Ticagrelor	Clopidogrel Responders - Ticagrelor to Clopidogrel	Clopidogrel Responders - Ticagrelor to Ticagrelor	Total
Number of Participants	20	21	13	16	14	14	98
Age, Continuous [units: year] Mean (Standard Deviation)	67.25 (8.12)	64.57 (6.31)	65.46 (8.68)	64.56 (8.56)	63.21 (9.23)	61.57 (8.22)	64.8 (7.95)
Gender, Male/Female [units: Participants]							
Female	5	8	3	2	3	1	22
Male	15	13	10	14	11	13	76

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Proportion of Clopidogrel Non-responders Who Responded to Clopidogrel or Ticagrelor. - Comparing Ticag. (Day 28 of Clop. to Ticag., and Day 14 of Ticag. to Clop.) Versus Clop. (Day 14 of Clop. to Ticag., and Day 28 of Ticag. to Clop.)
Measure Description	The primary definition of response to treatment is IPA >10% post treatment. The response is reported as percentage of participants of each treatment. Please refer to the protocol section for details about the interventions administered. IPA(%)=(PAb-PAt)/PAb*100. PA (platelet aggregation) is measured by LTA (Light Transmittance Aggregometry). PAb is the response at baseline (last measurement before study drug) and PAt is a response at post-treatment. IPA=0% means no PA inhibition and 100% means 100% PA inhibition.
Time Frame	Day 14 and Day 28, 4 Hrs Post Dose.
Safety Issue?	No

Analysis Population Description

Intent-to-treat analysis set: included patients who were assigned to a cohort, randomised to a treatment group, received at least one dose of study drug, and contributed post baseline data. 32 subjects had IPA data; but 1 subject missing a treatment arm, did not qualify for McNemar's test.

Reporting Groups

	Description
Non-responder: Ticagrelor	patients with an absolute difference of less than or equal to 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 μM ADP used as the agonist

	Description
Non-responder: Clopidogrel	patients with an absolute difference of less than or equal to 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist

Measured Values

	Non-responder: Ticagrelor	Non-responder: Clopidogrel
Number of Participants Analyzed	31	31
Proportion of Clopidogrel Non-responders Who Responded to Clopidogrel or Ticagrelor. - Comparing Ticag. (Day 28 of Clop. to Ticag., and Day 14 of Ticag. to Clop.) Versus Clop. (Day 14 of Clop. to Ticag., and Day 28 of Ticag. to Clop.) [units: Percent of Participants]	100	93.8

2. Primary Outcome Measure:

Measure Title	Proportion of Clopidogrel Non-responders Who Responded to Clopidogrel or Ticagrelor. - Comparing Ticag. (Day 28 of Clop. to Ticag., and Day 14 of Ticag. to Clop.) Versus Clop. (Day 14 of Clop. to Ticag., and Day 28 of Ticag. to Clop.
Measure Description	The secondary definition of response to treatment is IPA >50% post treatment. The response is reported as percentage of participants of each treatment. Please refer to the protocol section for details about the interventions administered. IPA(%)=(PAb-PAt)/PAb*100. PA (platelet aggregation) is measured by LTA (Light Transmittance Aggregometry). PAb is the response at baseline (last measurement before study drug) and PAt is a response at post-treatment. IPA=0% means no PA inhibition and 100% means 100% PA inhibition.
Time Frame	Day 14, and day 28, 4 hours post dose
Safety Issue?	No

Analysis Population Description

Intent-to-treat analysis set: included patients who were assigned to a cohort, randomised to a treatment group, received at least one dose of study drug, and contributed post baseline data. 32 subjects had IPA data; but 1 subject missing a treatment arm, did not qualify for McNemar's test.

Reporting Groups

	Description
Non-responder: Ticagrelor	patients with an absolute difference of less than or equal to 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist
Non-responder: Clopidogrel	patients with an absolute difference of less than or equal to 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist

Measured Values

	Non-responder: Ticagrelor	Non-responder: Clopidogrel
Number of Participants Analyzed	31	31
Proportion of Clopidogrel Non-responders Who Responded to Clopidogrel or Ticagrelor. - Comparing Ticag. (Day 28 of Clop. to Ticag., and Day 14 of Ticag. to Clop.) Versus Clop. (Day 14 of Clop. to Ticag., and Day 28 of Ticag. to Clop. [units: Percent of participants]	81.3	25.0

3. Secondary Outcome Measure:

Measure Title	Clopidogrel Responders Final Extent IPA Post Switching Treatment - Comparing Ticagrelor to Ticagrelor Versus Ticagrelor to Clopidogrel on Day 15
Measure Description	IPA(%)=(PAb-PAt)/PAb*100. PA (platelet aggregation) is measured by LTA (Light Transmittance Aggregometry). PAb is the response at baseline (last measurement before study drug) and PAt is a response at post-treatment. IPA=0% means no PA inhibition and 100% means 100% PA inhibition. Please refer to the protocol section for details about the interventions administered.
Time Frame	Day 15, 4 hrs post switching
Safety Issue?	No

Analysis Population Description

Intent-to-treat analysis set: included patients who were assigned to a cohort, randomised to a treatment group, received at least one dose of study drug, and contributed post baseline data.

Reporting Groups

	Description
Responder: Ticagrelor	patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 μM ADP used as the agonist
Responder: Clopidogrel	patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 μM ADP used as the agonist

Measured Values

	Responder: Ticagrelor	Responder: Clopidogrel
Number of Participants Analyzed	12	10

	Responder: Ticagrelor	Responder: Clopidogrel
Clopidogrel Responders Final Extent IPA Post Switching Treatment - Comparing Ticagrelor to Ticagrelor Versus Ticagrelor to Clopidogrel on Day 15 [units: Percent] Least Squares Mean (95% Confidence Interval)	66.7 (49.7 to 83.7)	65.3 (46.5 to 84.2)

4. Secondary Outcome Measure:

Measure Title	Clopidogrel Responders Final Extent IPA Post Switching Treatment - Comparing Ticagrelor to Ticagrelor Versus Ticagrelor to Clopidogrel on Day 28
Measure Description	IPA(%)=(PAb-PAt)/PAb*100. PA (platelet aggregation) is measured by LTA (Light Transmittance Aggregometry). PAb is the response at baseline (last measurement before study drug) and PAt is a response at post-treatment. IPA=0% means no PA inhibition and 100% means 100% PA inhibition. Please refer to the protocol section for details about the interventions administered.
Time Frame	4 hrs post first dose on day 28
Safety Issue?	No

Analysis Population Description

Intent-to-treat analysis set: included patients who were assigned to a cohort, randomised to a treatment group, received at least one dose of study drug, and contributed post baseline data.

Reporting Groups

	Description
Responder: Ticagrelor	patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist
Responder: Clopidogrel	patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist

Measured Values

	Responder: Ticagrelor	Responder: Clopidogrel
Number of Participants Analyzed	11	10
Clopidogrel Responders Final Extent IPA Post Switching Treatment - Comparing Ticagrelor to Ticagrelor Versus Ticagrelor to Clopidogrel on Day 28 [units: Percent] Least Squares Mean (95% Confidence Interval)	91.0 (77.1 to 104.9)	61.2 (46.4 to 76.0)

5. Secondary Outcome Measure:

Measure Title	Clopidogrel Responders Final Extent IPA Post Switching Treatment - Comparing Clopidogrel to Clopidogrel Versus Clopidogrel to Ticagrelor on Day 15
Measure Description	IPA(%)=(PAb-PAt)/PAb*100. PA (platelet aggregation) is measured by LTA (Light Transmittance Aggregometry). PAb is the response at baseline (last measurement before study drug) and PAt is a response at post-treatment. IPA=0% means no PA inhibition and 100% means 100% PA inhibition. Please refer to the protocol section for details about the interventions administered.
Time Frame	Day 15, 4 hrs post switching
Safety Issue?	No

Analysis Population Description

Intent-to-treat analysis set: included patients who were assigned to a cohort, randomised to a treatment group, received at least one dose of study drug, and contributed post baseline data.

Reporting Groups

	Description
Responder: Ticagrelor	patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist
Responder: Clopidogrel	patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist

Measured Values

	Responder: Ticagrelor	Responder: Clopidogrel
Number of Participants Analyzed	14	13
Clopidogrel Responders Final Extent IPA Post Switching Treatment - Comparing Clopidogrel to Clopidogrel Versus Clopidogrel to Ticagrelor on Day 15 [units: Percent] Least Squares Mean (95% Confidence Interval)	95.0 (87.7 to 102.4)	48.5 (40.8 to 56.2)

6. Secondary Outcome Measure:

Measure Title	Clopidogrel Responders Final Extent IPA Post Switching Treatment - Comparing Clopidogrel to Clopidogrel Versus Clopidogrel to Ticagrelor on Day 28
Measure Description	IPA(%)=(PAb-PAt)/PAb*100. PA (platelet aggregation) is measured by LTA (Light Transmittance Aggregometry). PAb is the response at baseline (last measurement before study drug) and PAt is a response at post-treatment. IPA=0% means no PA inhibition and 100% means 100% PA inhibition. Please refer to the protocol section for details about the interventions administered.
Time Frame	4 hrs post first dose on day 28
Safety Issue?	No

Analysis Population Description

Intent-to-treat analysis set: included patients who were assigned to a cohort, randomised to a treatment group, received at least one dose of study drug, and contributed post baseline data.

Reporting Groups

	Description
Responder: Ticagrelor	patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist
Responder: Clopidogrel	patients with an absolute difference greater than 10% between baseline and post-treatment platelet aggregation (maximum extent) with 20 µM ADP used as the agonist

Measured Values

	Responder: Ticagrelor	Responder: Clopidogrel
Number of Participants Analyzed	14	13
Clopidogrel Responders Final Extent IPA Post Switching Treatment - Comparing Clopidogrel to Clopidogrel Versus Clopidogrel to Ticagrelor on Day 28 [units: Percent] Least Squares Mean (95% Confidence Interval)	77.4 (67.0 to 87.8)	60.8 (49.9 to 71.7)

Reported Adverse Events

Time Frame	Switching Period - first 24 hrs (Day 15), patients switched study medication (from clop. to ticag. or vice versa). Non-Switching Period – Day 1-14 and Day 16-28.

Additional Description	Analysis included all randomized subjects.

Reporting Groups

	Description
Clopidogrel Non-Responders/Non-Switching Period: Ticagrelor	included non-responders exposed to ticagrelor on Day 1-14, Day 16-28.
Clopidogrel Non-Responders/Non-Switching Period: Clopidogrel	included non-responders exposed to clopidogrel on Day 1-14, Day 16-28.
Clop. Non-Responders/Switching Period:Ticagrelor-Clopidogrel	included non-responders exposed to ticagrelor switching to clopidogrel on Day 15.
Clop. Non-Responders/Switching Period: Clopidogrel-Ticagrelor	included non-responders exposed to clopidogrel switching to ticagrelor on Day 15.
Clop. Responders/Non-Switching Period: Ticagrelor	included responders exposed to ticagrelor on Day 1-14, Day 16-28.
Clop. Responders/Non-Switching Period: Clopidogrel	included responders exposed to clopidogrel on Day 1-14, Day 16-28.
Clop. Responders/Switching Period: Ticagrelor-Clopidogrel	included responders exposed to ticagrelor switching to clopidogrel on Day 15.
Clop. Responders/Switching Period: Clopidogrel-Ticagrelor	included responders exposed to clopidogrel switching to ticagrelor on Day 15.

Serious Adverse Events

	Clopidogrel Non-Responders/ Non-Switching Period: Ticagrelor	Clopidogrel Non-Responders/ Non-Switching Period: Clopidogrel	Clop. Non-Responders/ Switching Period:Ticagrelor-Clopidogrel	Clop. Non-Responders/ Switching Period: Clopidogrel-Ticagrelor	Clop. Responders/ Non-Switching Period: Ticagrelor	Clop. Responders/ Non-Switching Period: Clopidogrel
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Total	2/39 (5.13%)	0/38 (0%)	0/18 (0%)	0/18 (0%)	2/44 (4.55%)	0/42 (0%)
Cardiac disorders						
Atrial Fibrillation [A] †	0/39 (0%)	0/38 (0%)	0/18 (0%)	0/18 (0%)	1/44 (2.27%)	0/42 (0%)
Bradycardia [A] †	0/39 (0%)	0/38 (0%)	0/18 (0%)	0/18 (0%)	1/44 (2.27%)	0/42 (0%)
Myocardial Infarction [A] †	1/39 (2.56%)	0/38 (0%)	0/18 (0%)	0/18 (0%)	0/44 (0%)	0/42 (0%)

	Clopidogrel Non-Responders/ Non-Switching Period: Ticagrelor	Clopidogrel Non-Responders/ Non-Switching Period: Clopidogrel	Clop. Non-Responders/ Switching Period:Ticagrelor-Clopidogrel	Clop. Non-Responders/ Switching Period: Clopidogrel-Ticagrelor	Clop. Responders/ Non-Switching Period: Ticagrelor	Clop. Responders/ Non-Switching Period: Clopidogrel
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Ventricular Extrasystoles [A] †	0/39 (0%)	0/38 (0%)	0/18 (0%)	0/18 (0%)	1/44 (2.27%)	0/42 (0%)
Vascular disorders						
Hypotension [A] †	1/39 (2.56%)	0/38 (0%)	0/18 (0%)	0/18 (0%)	0/44 (0%)	0/42 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 11.1

	Clop. Responders/Switching Period: Ticagrelor-Clopidogrel	Clop. Responders/Switching Period: Clopidogrel-Ticagrelor
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/13 (0%)	0/16 (0%)
Cardiac disorders		
Atrial Fibrillation [A] †	0/13 (0%)	0/16 (0%)
Bradycardia [A] †	0/13 (0%)	0/16 (0%)
Myocardial Infarction [A] †	0/13 (0%)	0/16 (0%)
Ventricular Extrasystoles [A] †	0/13 (0%)	0/16 (0%)
Vascular disorders		
Hypotension [A] †	0/13 (0%)	0/16 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 11.1

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Clopidogrel Non-Responders/ Non-Switching Period: Ticagrelor	Clopidogrel Non-Responders/ Non-Switching Period: Clopidogrel	Clop. Non-Responders/ Switching Period:Ticagrelor-Clopidogrel	Clop. Non-Responders/ Switching Period: Clopidogrel-Ticagrelor	Clop. Responders/ Non-Switching Period: Ticagrelor	Clop. Responders/ Non-Switching Period: Clopidogrel
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Total	13/39 (33.33%)	13/39 (33.33%)	1/18 (5.56%)	4/18 (22.22%)	19/44 (43.18%)	14/42 (33.33%)
Gastrointestinal disorders						
DIARRHOEA [A] †	2/39 (5.13%)	1/38 (2.63%)	0/18 (0%)	0/18 (0%)	1/44 (2.27%)	2/42 (4.76%)
DYSPEPSIA [A] †	0/39 (0%)	0/38 (0%)	0/18 (0%)	0/18 (0%)	1/44 (2.27%)	4/42 (9.52%)
NAUSEA [A] †	0/39 (0%)	1/38 (2.63%)	0/18 (0%)	0/18 (0%)	0/44 (0%)	4/42 (9.52%)
General disorders						
CHEST DISCOMFORT [A] †	0/39 (0%)	0/38 (0%)	1/18 (5.56%)	0/18 (0%)	0/44 (0%)	0/42 (0%)
FATIGUE [A] †	0/39 (0%)	1/38 (2.63%)	0/18 (0%)	0/18 (0%)	1/44 (2.27%)	2/42 (4.76%)
VESSEL PUNCTURE SITE HAEMATOMA [A] †	0/39 (0%)	0/38 (0%)	0/18 (0%)	1/18 (5.56%)	2/44 (4.55%)	2/42 (4.76%)
Injury, poisoning and procedural complications						
CONTUSION [A] †	0/39 (0%)	0/38 (0%)	0/18 (0%)	0/18 (0%)	3/44 (6.82%)	0/42 (0%)
TRAUMATIC HAEMATOMA [A] †	0/39 (0%)	2/38 (5.26%)	0/18 (0%)	0/18 (0%)	2/44 (4.55%)	0/42 (0%)
Musculoskeletal and connective tissue disorders						
ARTHRALGIA [A] †	0/39 (0%)	0/38 (0%)	0/18 (0%)	0/18 (0%)	0/44 (0%)	1/42 (2.38%)
MYALGIA [A] †	0/39 (0%)	1/38 (2.63%)	0/18 (0%)	0/18 (0%)	0/44 (0%)	0/42 (0%)
Nervous system disorders						
DIZZINESS [A] †	1/39 (2.56%)	3/38 (7.89%)	0/18 (0%)	2/18 (11.11%)	1/44 (2.27%)	1/42 (2.38%)
HEADACHE [A] †	2/39 (5.13%)	1/38 (2.63%)	0/18 (0%)	0/18 (0%)	0/44 (0%)	1/42 (2.38%)

	Clopidogrel Non-Responders/ Non-Switching Period: Ticagrelor	Clopidogrel Non-Responders/ Non-Switching Period: Clopidogrel	Clop. Non-Responders/ Switching Period:Ticagrelor-Clopidogrel	Clop. Non-Responders/ Switching Period: Clopidogrel-Ticagrelor	Clop. Responders/ Non-Switching Period: Ticagrelor	Clop. Responders/ Non-Switching Period: Clopidogrel
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
PARAESTHESIA [A] †	0/39 (0%)	2/38 (5.26%)	0/18 (0%)	0/18 (0%)	1/44 (2.27%)	0/42 (0%)
RESTLESS LEGS SYNDROME [A] †	0/39 (0%)	1/38 (2.63%)	0/18 (0%)	1/18 (5.56%)	0/44 (0%)	0/42 (0%)
Respiratory, thoracic and mediastinal disorders						
DYSPNOEA [A] †	7/39 (17.95%)	3/38 (7.89%)	1/18 (5.56%)	2/18 (11.11%)	6/44 (13.64%)	0/42 (0%)
EPISTAXIS [A] †	0/39 (0%)	0/38 (0%)	0/18 (0%)	0/18 (0%)	3/44 (6.82%)	0/42 (0%)
Skin and subcutaneous tissue disorders						
INCREASED TENDENCY TO BRUISE [A] †	3/39 (7.69%)	1/38 (2.63%)	0/18 (0%)	0/18 (0%)	2/44 (4.55%)	2/42 (4.76%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.1)

	Clop. Responders/Switching Period: Ticagrelor-Clopidogrel	Clop. Responders/Switching Period: Clopidogrel-Ticagrelor
	Affected/At Risk (%)	Affected/At Risk (%)
Total	2/13 (15.38%)	1/16 (6.25%)
Gastrointestinal disorders		
DIARRHOEA [A] †	0/13 (0%)	0/16 (0%)
DYSPEPSIA [A] †	0/13 (0%)	0/16 (0%)
NAUSEA [A] †	0/13 (0%)	0/16 (0%)
General disorders		
CHEST DISCOMFORT [A] †	0/13 (0%)	0/16 (0%)
FATIGUE [A] †	1/13 (7.69%)	0/16 (0%)

	Clop. Responders/Switching Period: Ticagrelor-Clopidogrel	Clop. Responders/Switching Period: Clopidogrel-Ticagrelor
	Affected/At Risk (%)	Affected/At Risk (%)
VESSEL PUNCTURE SITE HAEMATOMA [A] †	0/13 (0%)	0/16 (0%)
Injury, poisoning and procedural complications		
CONTUSION [A] †	0/13 (0%)	0/16 (0%)
TRAUMATIC HAEMATOMA [A] †	0/13 (0%)	0/16 (0%)
Musculoskeletal and connective tissue disorders		
ARTHRALGIA [A] †	1/13 (7.69%)	0/16 (0%)
MYALGIA [A] †	1/13 (7.69%)	0/16 (0%)
Nervous system disorders		
DIZZINESS [A] †	0/13 (0%)	0/16 (0%)
HEADACHE [A] †	0/13 (0%)	0/16 (0%)
PARAESTHESIA [A] †	0/13 (0%)	0/16 (0%)
RESTLESS LEGS SYNDROME [A] †	0/13 (0%)	0/16 (0%)
Respiratory, thoracic and mediastinal disorders		
DYSPNOEA [A] †	0/13 (0%)	0/16 (0%)
EPISTAXIS [A] †	0/13 (0%)	0/16 (0%)
Skin and subcutaneous tissue disorders		
INCREASED TENDENCY TO BRUISE [A] †	0/13 (0%)	1/16 (6.25%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.1)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

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

An Investigator agrees to provide a copy of the publication to AZ for review at least 60 days in advance of submission for publication. Investigators in multicenter (MC) studies agree to postpone MC publications until the earlier of the date of the first AZ-authorized MC publication or a period up to 18 months from study completion at all sites.

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