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Trial record **1 of 1** for: 39039039ACS2001

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Rivaroxaban in Combination With Aspirin Alone or With Aspirin and a Thienopyridine in Patients With Acute Coronary Syndromes (The ATLAS ACS TIMI 46 Trial)

This study has been completed.

Sponsor:
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Collaborator:
Bayer

Information provided by:
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

ClinicalTrials.gov Identifier:
NCT00402597

First received: November 21, 2006
Last updated: September 28, 2012
Last verified: September 2012
History of Changes

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Results First Received: July 25, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Acute Coronary Syndrome
Interventions:	Drug: Rivaroxaban/Placebo Drug: Placebo Drug: Rivaroxaban

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
NCT00402597: Study 39039039ACS2001 (ATLAS ACS TIMI 46 Trial) was conducted at 297 centers in 27 countries between 17 November 2006 and 19 September 2008. A total of 3576 patients were screened for study and 3491 patients were randomly assigned to treatment.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Of the 3576 patients screened for study, 85 patients were screening failures and 3491 patients were randomly assigned to treatment. All randomized patients were included in the intent-to-treat (ITT) analysis set and were eligible for efficacy analyses. Of the 3491 patients, 29 never took study drug, leaving 3462 patients valid for safety analysis.

Reporting Groups

	Description
Placebo	One placebo tablet twice daily for 6 months.
Riva 5 mg Total Daily Dose (TDD)	Rivaroxaban 5 mg (2.5 mg twice a day or 5 mg once daily)

Riva 10 mg TDD	Rivaroxaban 10 mg (5 mg twice a day or 10 mg once daily) for 6 months.
Riva 15 mg TDD	Rivaroxaban 15 mg (7.5 mg twice a day or 15 mg once daily) for 6 months.
Riva 20 mg TDD	Rivaroxaban 20 mg (10 mg twice a day or 20 mg once daily) for 6 months.

Participant Flow: Overall Study

	Placebo	Riva 5 mg Total Daily Dose (TDD)	Riva 10 mg TDD	Riva 15 mg TDD	Riva 20 mg TDD
STARTED	1153	307	1046	353	603
COMPLETED	962	261	834	279	479
NOT COMPLETED	191	46	212	74	124
Death	15	7	6	4	6
Adverse Event	81	18	106	39	71
Lost to Follow-up	8	1	8	2	3
Withdrawal by Subject	57	16	65	15	24
reason not specified	30	4	27	14	20

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Placebo	One placebo tablet twice daily for 6 months.
Riva 5 mg Total Daily Dose (TDD)	Rivaroxaban 5 mg (2.5 mg twice a day or 5 mg once daily)
Riva 10 mg TDD	Rivaroxaban 10 mg (5 mg twice a day or 10 mg once daily) for 6 months.
Riva 15 mg TDD	Rivaroxaban 15 mg (7.5 mg twice a day or 15 mg once daily) for 6 months.
Riva 20 mg TDD	Rivaroxaban 20 mg (10 mg twice a day or 20 mg once daily) for 6 months.
Total	Total of all reporting groups

Baseline Measures

	Placebo	Riva 5 mg Total Daily Dose (TDD)	Riva 10 mg TDD	Riva 15 mg TDD	Riva 20 mg TDD	Total
Number of Participants [units: participants]	1153	307	1046	353	603	3462
Age [units: participants]						
<=18 years	0	0	0	0	0	0
Between 18 and 65						

years	847	218	786	283	458	2592
>=65 years	306	89	260	70	145	870
Age [units: years] Mean (Standard Deviation)	57.8 (9.58)	58.1 (9.76)	57.2 (9.71)	56.4 (9.38)	57.4 (9.06)	57.4 (9.53)
Gender [units: participants]						
Female	272	78	228	67	143	788
Male	881	229	818	286	460	2674
Region of Enrollment [units: participants]						
Australia	75	14	73	15	29	206
Belgium	19	3	34	9	12	77
Brazil	11	0	26	0	0	37
Bulgaria	78	47	85	7	41	258
Canada	34	2	28	7	17	88
China	2	0	2	0	0	4
Czech Republic	48	0	58	33	41	180
Denmark	18	16	14	7	9	64
Finland	3	0	7	0	6	16
France	16	1	21	5	6	49
Germany	31	3	35	11	12	92
Hungary	11	0	14	7	4	36
Israel	43	0	26	16	11	96
Italy	43	3	56	17	17	136
Korea (South)	17	0	9	10	11	47
Netherlands	28	0	39	9	11	87
New Zealand	57	22	37	8	24	148
Norway	8	3	5	0	5	21
Poland	174	4	109	86	124	497
Russia	136	90	105	17	82	430
Slovakia	49	1	32	13	21	116
South Africa	6	0	7	0	4	17
Spain	35	5	36	12	15	103
Sweden	13	2	17	6	9	47
Ukraine	57	21	37	11	33	159
United Kingdom	9	1	19	15	8	52
United States	132	69	115	32	51	399

Outcome Measures

Hide All Outcome Measures

1. Primary: Thrombolysis in Myocardial Infarction (TIMI) Clinically Significant Bleeding Events (Primary Safety) [Time Frame: Day 1 to Day 210]

Measure Type	Primary
Measure Title	Thrombolysis in Myocardial Infarction (TIMI) Clinically Significant Bleeding Events (Primary Safety)
Measure Description	The number of patients with a first occurrence of a TIMI clinically significant bleeding event that occurred from the time of randomization to the time of the last patient contact. TIMI clinically significant bleeding events included TIMI minor bleeding events, TIMI major bleeding events, or any bleeding that required medical attention.
Time Frame	Day 1 to Day 210
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The safety population consisted of all randomized patients who took at least 1 dose of study medication after randomization during the double-blind treatment period.

Reporting Groups

	Description
Placebo	One Placebo tablet twice daily for 6 months.
Riva 5 mg Total Daily Dose (TDD)	Rivaroxaban 5 mg (2.5 mg twice a day or 5 mg once daily) for 6 months.
Riva 10 mg TDD	Rivaroxaban 10 mg (5 mg twice a day or 10 mg once daily) for 6 months.
Riva 15 mg TDD	Rivaroxaban 15 mg (7.5 mg twice a day or 15 mg once daily) for 6 months.
Riva 20 mg TDD	Rivaroxaban 20 mg (10 mg twice a day or 20 mg once daily) for 6 months.

Measured Values

	Placebo	**Riva 5 mg Total Daily Dose (TDD)**	**Riva 10 mg TDD**	**Riva 15 mg TDD**	**Riva 20 mg TDD**
Number of Participants Analyzed [units: participants]	**1153**	**307**	**1046**	**353**	**603**
Thrombolysis in Myocardial Infarction (TIMI) Clinically Significant Bleeding Events (Primary Safety) [units: Patients]	**36**	**17**	**109**	**43**	**89**

No statistical analysis provided for Thrombolysis in Myocardial Infarction (TIMI) Clinically Significant Bleeding Events (Primary Safety)

2. Primary: The Composite Endpoint of All Cause Death, Myocardial Infarction (MI) (Including Repeat MI), Stroke (Ischemic, Hemorrhagic or Unknown), or Severe Recurrent Ischemia Requiring Revascularization (Primary Efficacy) [Time Frame: Day 1 to Day 210]

Measure Type	Primary
Measure Title	The Composite Endpoint of All Cause Death, Myocardial Infarction (MI) (Including Repeat MI), Stroke (Ischemic, Hemorrhagic or Unknown), or Severe Recurrent Ischemia Requiring Revascularization (Primary Efficacy)
Measure Description	The number of patients who died due to any cause or had a first occurrence of MI (including repeat MI) or stroke (ischemic, hemorrhagic or unknown) or severe recurrent ischemia requiring revascularization from the time of randomization to the last date of patient contact.
Time Frame	Day 1 to Day 210
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The intent-to-treat (ITT) population consisted of all patients who were randomized to treatment, regardless of study drug intake.

Reporting Groups

	Description
Placebo	One Placebo tablet twice daily for 6 months.
Riva 5 mg Total Daily Dose (TDD)	Rivaroxaban 5 mg (2.5 mg twice a day or 5 mg once daily) for 6 months.
Riva 10 mg TDD	Rivaroxaban 10 mg (5 mg twice a day or 10 mg once daily) for 6 months.
Riva 15 mg TDD	Rivaroxaban 15 mg (7.5 mg twice a day or 15 mg once daily) for 6 months.
Riva 20 mg TDD	Rivaroxaban 20 mg (10 mg twice a day or 20 mg once daily) for 6 months.

Measured Values

	Placebo	**Riva 5 mg Total Daily Dose (TDD)**	**Riva 10 mg TDD**	**Riva 15 mg TDD**	**Riva 20 mg TDD**
Number of Participants Analyzed [units: participants]	**1160**	**308**	**1056**	**356**	**611**
The Composite Endpoint of All Cause Death, Myocardial Infarction (MI) (Including Repeat MI), Stroke (Ischemic, Hemorrhagic or Unknown), or Severe Recurrent Ischemia Requiring Revascularization (Primary Efficacy) [units: Patients]	**83**	**23**	**55**	**27**	**36**

No statistical analysis provided for The Composite Endpoint of All Cause Death, Myocardial Infarction (MI) (Including Repeat MI), Stroke (Ischemic, Hemorrhagic or Unknown), or Severe Recurrent Ischemia Requiring Revascularization (Primary Efficacy)

3. Secondary: The Composite Endpoint of Death (All Cause), Myocardial Infarction (MI) (or Repeat MI), or Stroke [Time Frame: Day 1 to Day 210]

Measure Type	Secondary
Measure Title	The Composite Endpoint of Death (All Cause), Myocardial Infarction (MI) (or Repeat MI), or Stroke
Measure Description	The number of patients who died due to any cause or had a first occurrence of MI (or repeat MI) or stroke from the time of randomization to the last date of patient contact.
Time Frame	Day 1 to Day 210
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The ITT population consisted of all patients who were randomized to treatment, regardliess of study drug intake.

Reporting Groups

	Description
Placebo	One Placebo tablet twice daily for 6 months.

Riva 5 mg Total Daily Dose (TDD)	Rivaroxaban 5 mg (2.5 mg twice a day or 5 mg once daily) for 6 months.
Riva 10 mg TDD	Rivaroxaban 10 mg (5 mg twice a day or 10 mg once daily) for 6 months.
Riva 15 mg TDD	Rivaroxaban 15 mg (7.5 mg twice a day or 15 mg once daily) for 6 months.
Riva 20 mg TDD	Rivaroxaban 20 mg (10 mg twice a day or 20 mg once daily) for 6 months.

Measured Values

	Placebo	Riva 5 mg Total Daily Dose (TDD)	Riva 10 mg TDD	Riva 15 mg TDD	Riva 20 mg TDD
Number of Participants Analyzed [units: participants]	**1160**	**308**	**1056**	**356**	**611**
The Composite Endpoint of Death (All Cause), Myocardial Infarction (MI) (or Repeat MI), or Stroke [units: Patients]	**66**	**18**	**40**	**21**	**22**

No statistical analysis provided for The Composite Endpoint of Death (All Cause), Myocardial Infarction (MI) (or Repeat MI), or Stroke

4. Secondary: The Composite Endpoint of Cardiovascular Death, Myocardial Infarction (MI), or Stroke [Time Frame: Day 1 to Day 210]

Measure Type	Secondary
Measure Title	The Composite Endpoint of Cardiovascular Death, Myocardial Infarction (MI), or Stroke
Measure Description	The number of patients with the composite endpoint of cardiovascular death or MI or stroke that occurred from the time of randomization to the last date of patient contact.
Time Frame	Day 1 to Day 210
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The ITT population consisted of all patients who were randomized to treatment regardless of study drug intake.

Reporting Groups

	Description
Placebo	One Placebo tablet twice daily for 6 months.
Riva 5 mg Total Daily Dose (TDD)	Rivaroxaban 5 mg (2.5 mg twice a day or 5 mg once daily) for 6 months.
Riva 10 mg TDD	Rivaroxaban 10 mg (5 mg twice a day or 10 mg once daily) for 6 months.
Riva 15 mg TDD	Rivaroxaban 15 mg (7.5 mg twice a day or 15 mg once daily) for 6 months.
Riva 20 mg TDD	Rivaroxaban 20 mg (10 mg twice a day or 20 mg once daily) for 6 months.

Measured Values

	Placebo	Riva 5 mg Total Daily Dose (TDD)	Riva 10 mg TDD	Riva 15 mg TDD	Riva 20 mg TDD
Number of Participants Analyzed [units: participants]	**1160**	**308**	**1056**	**356**	**611**
The Composite Endpoint of Cardiovascular Death, Myocardial Infarction (MI), or Stroke	**63**	**18**	**40**	**21**	**21**

[units: Patients]					

No statistical analysis provided for The Composite Endpoint of Cardiovascular Death, Myocardial Infarction (MI), or Stroke

5. Secondary: The Number of Deaths (All Cause) [Time Frame: Day 1 to Day 210]

Measure Type	Secondary
Measure Title	The Number of Deaths (All Cause)
Measure Description	The number of patients who died due to any cause from the time of randomization to the last date of patient contact.
Time Frame	Day 1 to Day 210
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The ITT population consisted of all patients who were randomized to treatment, regardless of study drug intake.

Reporting Groups

	Description
Placebo	One Placebo tablet twice daily for 6 months.
Riva 5 mg Total Daily Dose (TDD)	Rivaroxaban 5 mg (2.5 mg twice a day or 5 mg once daily) for 6 months.
Riva 10 mg TDD	Rivaroxaban 10 mg (5 mg twice a day or 10 mg once daily) for 6 months.
Riva 15 mg TDD	Rivaroxaban 15 mg (7.5 mg twice a day or 15 mg once daily) for 6 months.
Riva 20 mg TDD	Rivaroxaban 20 mg (10 mg twice a day or 20 mg once daily) for 6 months.

Measured Values

	Placebo	**Riva 5 mg Total Daily Dose (TDD)**	**Riva 10 mg TDD**	**Riva 15 mg TDD**	**Riva 20 mg TDD**
Number of Participants Analyzed [units: participants]	**1160**	**308**	**1056**	**356**	**611**
The Number of Deaths (All Cause) [units: Patients]	**18**	**11**	**9**	**4**	**9**

No statistical analysis provided for The Number of Deaths (All Cause)

6. Secondary: The Composite Endpoint of Death (All Cause), MI (or reMI), Stroke, Severe Recurrent Ischemia Requiring Revascularization, or Thrombolysis in Myocardial Infarction (TIMI) (Major or Minor Bleeding) to Assess the Net Clinical Benefit [Time Frame: Day 1 to Day 210]

Measure Type	Secondary
Measure Title	The Composite Endpoint of Death (All Cause), MI (or reMI), Stroke, Severe Recurrent Ischemia Requiring Revascularization, or Thrombolysis in Myocardial Infarction (TIMI) (Major or Minor Bleeding) to Assess the Net Clinical Benefit
Measure Description	The number of patients who died due to any cause or had a first occurrence of MI (or repeat MI), or stroke, or severe recurrent ischemia requiring revascularization, or TIMI (major or minor bleeding) from the time of randomization to the last date of patient contact to assess the net clinical benefit of rivaroxaban.

Time Frame	Day 1 to Day 210
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The ITT population consisted of all patients who were randomized to treatment, regardless of study drug intake.

Reporting Groups

	Description
Placebo	One Placebo tablet twice daily for 6 months.
Riva 5 mg Total Daily Dose (TDD)	Rivaroxaban 5 mg (2.5 mg twice a day or 5 mg once daily) for 6 months.
Riva 10 mg TDD	Rivaroxaban 10 mg (5 mg twice a day or 10 mg once daily) for 6 months.
Riva 15 mg TDD	Rivaroxaban 15 mg (7.5 mg twice a day or 15 mg once daily) for 6 months.
Riva 20 mg TDD	Rivaroxaban 20 mg (10 mg twice a day or 20 mg once daily) for 6 months.

Measured Values

	Placebo	Riva 5 mg Total Daily Dose (TDD)	Riva 10 mg TDD	Riva 15 mg TDD	Riva 20 mg TDD
Number of Participants Analyzed [units: participants]	**1160**	**308**	**1056**	**356**	**611**
The Composite Endpoint of Death (All Cause), MI (or reMI), Stroke, Severe Recurrent Ischemia Requiring Revascularization, or Thrombolysis in Myocardial Infarction (TIMI) (Major or Minor Bleeding) to Assess the Net Clinical Benefit [units: Patients]	**88**	**24**	**71**	**35**	**48**

No statistical analysis provided for The Composite Endpoint of Death (All Cause), MI (or reMI), Stroke, Severe Recurrent Ischemia Requiring Revascularization, or Thrombolysis in Myocardial Infarction (TIMI) (Major or Minor Bleeding) to Assess the Net Clinical Benefit

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Only Treatment-Emergent Adverse Events are presented in the following sections, called as Frequent Adverse Events and Serious Adverse Events

Reporting Groups

	Description
Placebo	One placebo tablet twice daily for 6 months.
Riva 5 mg Total Daily Dose (TDD)	Rivaroxaban 5 mg (2.5 mg twice a day or 5 mg once daily) for 6 months.
Riva 10 mg TDD	Rivaroxaban 10 mg (5 mg twice a day or 10 mg once daily) for 6 months.
Riva 15 mg TDD	Rivaroxaban 15 mg (7.5 mg twice a day or 15 mg once daily) for 6 months.
Riva 20 mg TDD	Rivaroxaban 20 mg (10 mg twice a day or 20 mg once daily) for 6 months.

Serious Adverse Events

	Placebo	Riva 5 mg Total Daily Dose (TDD)	Riva 10 mg TDD	Riva 15 mg TDD	Riva 20 mg TDD
Total, serious adverse events					
# participants affected / at risk	**247/1153 (21.42%)**	**74/307 (24.10%)**	**208/1046 (19.89%)**	**72/353 (20.40%)**	**128/603 (21.23%)**
Blood and lymphatic system disorders					
Anaemia * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**3/1046 (0.29%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Haemorrhagic Anaemia * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Iron Deficiency Anaemia * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**1/603 (0.17%)**
Normochromic Normocytic Anaemia * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Thrombocythaemia * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Thrombocytopenia * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Cardiac disorders					
Acute Coronary Syndrome * 1					
# participants affected / at risk	**3/1153 (0.26%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**2/603 (0.33%)**
Acute Myocardial Infarction * 1					
# participants affected / at risk	**28/1153 (2.43%)**	**6/307 (1.95%)**	**13/1046 (1.24%)**	**8/353 (2.27%)**	**5/603 (0.83%)**
Angina Pectoris * 1					
# participants affected / at risk	**22/1153 (1.91%)**	**4/307 (1.30%)**	**16/1046 (1.53%)**	**4/353 (1.13%)**	**10/603 (1.66%)**
Angina Unstable * 1					
# participants affected / at risk	**42/1153 (3.64%)**	**12/307 (3.91%)**	**23/1046 (2.20%)**	**11/353 (3.12%)**	**21/603 (3.48%)**
Arteriosclerosis Coronary Artery * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Arteriospasm Coronary * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Atrial Fibrillation * 1					
# participants affected / at risk	**7/1153 (0.61%)**	**5/307 (1.63%)**	**6/1046 (0.57%)**	**2/353 (0.57%)**	**1/603 (0.17%)**
Atrial Flutter * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**3/1046 (0.29%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Atrioventricular Block Second Degree * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Bradycardia * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**2/1046 (0.19%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Cardiac Arrest * 1					

# participants affected / at risk	2/1153 (0.17%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	3/603 (0.50%)
Cardiac Failure * 1					
# participants affected / at risk	6/1153 (0.52%)	1/307 (0.33%)	6/1046 (0.57%)	1/353 (0.28%)	0/603 (0.00%)
Cardiac Failure Acute * 1					
# participants affected / at risk	1/1153 (0.09%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Cardiac Failure Congestive * 1					
# participants affected / at risk	0/1153 (0.00%)	3/307 (0.98%)	1/1046 (0.10%)	3/353 (0.85%)	1/603 (0.17%)
Cardio-Respiratory Arrest * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Cardiogenic Shock * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Cardiomyopathy * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Coronary Artery Disease * 1					
# participants affected / at risk	5/1153 (0.43%)	0/307 (0.00%)	3/1046 (0.29%)	1/353 (0.28%)	0/603 (0.00%)
Coronary Artery Insufficiency * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Coronary Artery Occlusion * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Coronary Artery Stenosis * 1					
# participants affected / at risk	1/1153 (0.09%)	1/307 (0.33%)	0/1046 (0.00%)	2/353 (0.57%)	0/603 (0.00%)
Dressler's Syndrome * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	1/603 (0.17%)
Intracardiac Thrombus * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Left Ventricular Dysfunction * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Left Ventricular Failure * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	1/353 (0.28%)	0/603 (0.00%)
Myocardial Infarction * 1					
# participants affected / at risk	5/1153 (0.43%)	3/307 (0.98%)	6/1046 (0.57%)	3/353 (0.85%)	8/603 (1.33%)
Myocardial Ischaemia * 1					
# participants affected / at risk	6/1153 (0.52%)	1/307 (0.33%)	12/1046 (1.15%)	1/353 (0.28%)	2/603 (0.33%)
Palpitations * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	3/1046 (0.29%)	1/353 (0.28%)	0/603 (0.00%)
Parasystole * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Pericardial Effusion * 1					
# participants affected / at risk	2/1153 (0.17%)	0/307 (0.00%)	0/1046 (0.00%)	1/353 (0.28%)	1/603 (0.17%)
Pericarditis * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Postinfarction Angina * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Sick Sinus Syndrome * 1					

# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Sinus Bradycardia * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Ventricular Arrhythmia * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	1/603 (0.17%)
Ventricular Dysfunction * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Ventricular Extrasystoles * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Ventricular Fibrillation * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	1/1046 (0.10%)	1/353 (0.28%)	0/603 (0.00%)
Ventricular Tachycardia * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	2/1046 (0.19%)	0/353 (0.00%)	1/603 (0.17%)
Congenital, familial and genetic disorders					
Endocardial Fibroelastosis * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Ear and labyrinth disorders					
Vertigo * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	1/353 (0.28%)	0/603 (0.00%)
Endocrine disorders					
Hyperthyroidism * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	1/353 (0.28%)	0/603 (0.00%)
Thyroid Disorder * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Eye disorders					
Conjunctival Haemorrhage * 1					
# participants affected / at risk	1/1153 (0.09%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Eye Haemorrhage * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	1/603 (0.17%)
Retinal Artery Thrombosis * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Vitreous Haemorrhage * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Gastrointestinal disorders					
Abdominal Pain * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	1/603 (0.17%)
Abdominal Pain Upper * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Anal Fissure * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Colitis Ischaemic * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Dry Mouth * 1					

# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Duodenal Ulcer * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Gastric Ulcer Haemorrhage * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Gastritis * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Gastrointestinal Haemorrhage * 1					
# participants affected / at risk	**2/1153 (0.17%)**	**1/307 (0.33%)**	**10/1046 (0.96%)**	**3/353 (0.85%)**	**6/603 (1.00%)**
Gastrooesophageal Reflux Disease * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Gingival Bleeding * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Haematemesis * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Haemorrhoidal Haemorrhage * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Inguinal Hernia * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Intestinal Haemorrhage * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**1/603 (0.17%)**
Lower Gastrointestinal Haemorrhage * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Melaena * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**3/353 (0.85%)**	**0/603 (0.00%)**
Nausea * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Oesophageal Haemorrhage * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Pancreatitis * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Pancreatitis Acute * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Peptic Ulcer * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Peptic Ulcer Haemorrhage * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Rectal Haemorrhage * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Retroperitoneal Haematoma * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Small Intestinal Haemorrhage * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**

Upper Gastrointestinal Haemorrhage * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Vomiting * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
General disorders					
Asthenia * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	3/603 (0.50%)
Catheter Site Haemorrhage * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Chest Discomfort * 1					
# participants affected / at risk	1/1153 (0.09%)	1/307 (0.33%)	2/1046 (0.19%)	0/353 (0.00%)	2/603 (0.33%)
Chest Pain * 1					
# participants affected / at risk	24/1153 (2.08%)	9/307 (2.93%)	17/1046 (1.63%)	2/353 (0.57%)	9/603 (1.49%)
Death * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Injection Site Phlebitis * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Non-Cardiac Chest Pain * 1					
# participants affected / at risk	11/1153 (0.95%)	4/307 (1.30%)	13/1046 (1.24%)	2/353 (0.57%)	5/603 (0.83%)
Puncture Site Haemorrhage * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	2/1046 (0.19%)	0/353 (0.00%)	1/603 (0.17%)
Puncture Site Reaction * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	1/353 (0.28%)	0/603 (0.00%)
Pyrexia * 1					
# participants affected / at risk	1/1153 (0.09%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	1/603 (0.17%)
Sudden Cardiac Death * 1					
# participants affected / at risk	3/1153 (0.26%)	1/307 (0.33%)	1/1046 (0.10%)	0/353 (0.00%)	1/603 (0.17%)
Sudden Death * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	2/1046 (0.19%)	1/353 (0.28%)	0/603 (0.00%)
Vessel Puncture Site Haemorrhage * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Hepatobiliary disorders					
Cholecystitis * 1					
# participants affected / at risk	2/1153 (0.17%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Cholecystitis Acute * 1					
# participants affected / at risk	1/1153 (0.09%)	1/307 (0.33%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Cholelithiasis * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	1/353 (0.28%)	2/603 (0.33%)
Immune system disorders					
Anaphylactic Shock * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Infections and infestations					
Abscess Limb * 1					

# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Acarodermatitis * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	1/353 (0.28%)	0/603 (0.00%)
Anal Abscess * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Bronchitis * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	1/603 (0.17%)
Bronchopneumonia * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	1/1046 (0.10%)	1/353 (0.28%)	2/603 (0.33%)
Cellulitis * 1					
# participants affected / at risk	2/1153 (0.17%)	1/307 (0.33%)	1/1046 (0.10%)	0/353 (0.00%)	1/603 (0.17%)
Cellulitis Orbital * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Cellulitis Pharyngeal * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Device Related Infection * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Erysipelas * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	1/603 (0.17%)
Gangrene * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Gastroenteritis * 1					
# participants affected / at risk	2/1153 (0.17%)	0/307 (0.00%)	2/1046 (0.19%)	0/353 (0.00%)	0/603 (0.00%)
Gastrointestinal Infection * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Gingival Abscess * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Implant Site Infection * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	1/353 (0.28%)	0/603 (0.00%)
Lobar Pneumonia * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Orchitis * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Pneumonia * 1					
# participants affected / at risk	3/1153 (0.26%)	1/307 (0.33%)	1/1046 (0.10%)	3/353 (0.85%)	0/603 (0.00%)
Post Procedural Infection * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Pyelonephritis * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	1/603 (0.17%)
Sepsis * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Staphylococcal Sepsis * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Urinary Tract Infection * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	1/353 (0.28%)	1/603 (0.17%)

Viral Infection * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Wound Infection * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Injury, poisoning and procedural complications					
Ankle Fracture * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Concussion * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Contusion * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Coronary Artery Restenosis * 1					
# participants affected / at risk	**2/1153 (0.17%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**2/603 (0.33%)**
Facial Bones Fracture * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Fall * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Head Injury * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Implantable Defibrillator Malfunction * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
In-Stent Coronary Artery Restenosis * 1					
# participants affected / at risk	**4/1153 (0.35%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Multiple Injuries * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Post Procedural Haematoma * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Radius Fracture * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Rib Fracture * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Road Traffic Accident * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Skull Fracture * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Subdural Haematoma * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**3/1046 (0.29%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Thrombosis in Device * 1					
# participants affected / at risk	**3/1153 (0.26%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Traumatic Haematoma * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Upper Limb Fracture * 1					

# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Vascular Pseudoaneurysm * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	5/1046 (0.48%)	1/353 (0.28%)	0/603 (0.00%)
Vascular Pseudoaneurysm Ruptured * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	1/353 (0.28%)	0/603 (0.00%)
Investigations					
Alanine Aminotransferase Increased * 1					
# participants affected / at risk	2/1153 (0.17%)	2/307 (0.65%)	1/1046 (0.10%)	0/353 (0.00%)	1/603 (0.17%)
Angiogram * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	1/353 (0.28%)	0/603 (0.00%)
Arteriogram Coronary * 1					
# participants affected / at risk	6/1153 (0.52%)	0/307 (0.00%)	3/1046 (0.29%)	1/353 (0.28%)	4/603 (0.66%)
Aspartate Aminotransferase Increased * 1					
# participants affected / at risk	0/1153 (0.00%)	2/307 (0.65%)	0/1046 (0.00%)	0/353 (0.00%)	1/603 (0.17%)
Blood Alkaline Phosphatase Increased * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	1/603 (0.17%)
Blood Bilirubin Increased * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	1/603 (0.17%)
Blood Pressure Increased * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
C-Reactive Protein Increased * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Chest X-Ray Abnormal * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Ejection Fraction Decreased * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	0/603 (0.00%)
Gamma-Glutamyltransferase Increased * 1					
# participants affected / at risk	0/1153 (0.00%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Haemoglobin Decreased * 1					
# participants affected / at risk	0/1153 (0.00%)	0/307 (0.00%)	0/1046 (0.00%)	2/353 (0.57%)	0/603 (0.00%)
Hepatic Enzyme Increased * 1					
# participants affected / at risk	1/1153 (0.09%)	1/307 (0.33%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Liver Function Test Abnormal * 1					
# participants affected / at risk	2/1153 (0.17%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Occult Blood * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	0/353 (0.00%)	0/603 (0.00%)
Metabolism and nutrition disorders					
Dehydration * 1					
# participants affected / at risk	2/1153 (0.17%)	0/307 (0.00%)	1/1046 (0.10%)	0/353 (0.00%)	1/603 (0.17%)
Diabetes Mellitus * 1					
# participants affected / at risk	1/1153 (0.09%)	0/307 (0.00%)	0/1046 (0.00%)	2/353 (0.57%)	0/603 (0.00%)

Hyperglycaemia * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Hypoglycaemia * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Musculoskeletal and connective tissue disorders					
Arthralgia * 1					
# participants affected / at risk	**2/1153 (0.17%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Arthritis Reactive * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Back Disorder * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Back Pain * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Haemarthrosis * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Musculoskeletal Chest Pain * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**3/603 (0.50%)**
Myalgia * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Osteoarthritis * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Pain in Extremity * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Spondyloarthropathy * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Breast Cancer in Situ * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Colon Cancer * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Colon Neoplasm * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Gastric Cancer * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Lung Neoplasm Malignant * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Meningioma * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Myelodysplastic Syndrome * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Ovarian Granulosa-Theca Cell Tumour * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**

Ovarian Neoplasm * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Rectal Cancer * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Nervous system disorders					
Brain Oedema * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Carotid Artery Stenosis * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Carpal Tunnel Syndrome * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Cerebral Infarction * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Cerebrovascular Accident * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Haemorrhage Intracranial * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Haemorrhagic Stroke * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Headache * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Ischaemic Cerebral Infarction * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Ischaemic Stroke * 1					
# participants affected / at risk	**2/1153 (0.17%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Lethargy * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Motor Neurone Disease * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Presyncope * 1					
# participants affected / at risk	**2/1153 (0.17%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Progressive Supranuclear Palsy * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Somnolence * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Subarachnoid Haemorrhage * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Syncope * 1					
# participants affected / at risk	**2/1153 (0.17%)**	**1/307 (0.33%)**	**2/1046 (0.19%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Vascular Encephalopathy * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Vertebrobasilar Insufficiency * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Psychiatric disorders					

Acute Psychosis * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Alcohol Withdrawal Syndrome * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Anxiety * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**2/353 (0.57%)**	**1/603 (0.17%)**
Depression * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Drug Dependence * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Major Depression * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**2/1046 (0.19%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Mental Status Changes * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Renal and urinary disorders					
Calculus Ureteric * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Calculus Urinary * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Cystitis Haemorrhagic * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Haematuria * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**3/603 (0.50%)**
Renal Colic * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Renal Failure Acute * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**2/603 (0.33%)**
Renal Haemorrhage * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Renal Impairment * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Reproductive system and breast disorders					
Benign Prostatic Hyperplasia * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Menometrorrhagia * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Menorrhagia * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Metrorrhagia * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**2/353 (0.57%)**	**0/603 (0.00%)**
Vaginal Haemorrhage * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Respiratory, thoracic and mediastinal disorders					

Acute Pulmonary Oedema * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Acute Respiratory Failure * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Asthma * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Bronchopneumopathy * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Chronic Obstructive Pulmonary Disease * 1					
# participants affected / at risk	**3/1153 (0.26%)**	**1/307 (0.33%)**	**2/1046 (0.19%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Cough * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Dyspnoea * 1					
# participants affected / at risk	**2/1153 (0.17%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Dyspnoea Exertional * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Epistaxis * 1					
# participants affected / at risk	**2/1153 (0.17%)**	**0/307 (0.00%)**	**4/1046 (0.38%)**	**3/353 (0.85%)**	**4/603 (0.66%)**
Haemoptysis * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Haemothorax * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Hyperventilation * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Pleural Effusion * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Productive Cough * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Pulmonary Embolism * 1					
# participants affected / at risk	**4/1153 (0.35%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Pulmonary Oedema * 1					
# participants affected / at risk	**4/1153 (0.35%)**	**3/307 (0.98%)**	**2/1046 (0.19%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Rales * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Respiratory Distress * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Skin and subcutaneous tissue disorders					
Pruritus * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Rash Papular * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Skin Ulcer * 1					

# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Surgical and medical procedures					
Angioplasty * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Catheterisation Cardiac * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Coronary Arterial Stent Insertion * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Coronary Artery Bypass * 1					
# participants affected / at risk	**3/1153 (0.26%)**	**2/307 (0.65%)**	**2/1046 (0.19%)**	**0/353 (0.00%)**	**2/603 (0.33%)**
Coronary Revascularisation * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**4/1046 (0.38%)**	**0/353 (0.00%)**	**2/603 (0.33%)**
Elective Procedure * 1					
# participants affected / at risk	**2/1153 (0.17%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Elective Surgery * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Implantable Defibrillator Insertion * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Percutaneous Coronary Intervention * 1					
# participants affected / at risk	**5/1153 (0.43%)**	**1/307 (0.33%)**	**6/1046 (0.57%)**	**1/353 (0.28%)**	**2/603 (0.33%)**
Surgery * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Vascular disorders					
Aortic Aneurysm * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Aortic Arteriosclerosis * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Aortic Stenosis * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Arteriosclerosis * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Arteriovenous Fistula * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Femoral Arterial Stenosis * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Femoral Artery Occlusion * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Haematoma * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Hypertension * 1					
# participants affected / at risk	**2/1153 (0.17%)**	**0/307 (0.00%)**	**5/1046 (0.48%)**	**0/353 (0.00%)**	**2/603 (0.33%)**
Hypertensive Crisis * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**

Iliac Artery Occlusion * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Intermittent Claudication * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Ischaemia * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**1/1046 (0.10%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Neovascularisation * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Orthostatic Hypotension * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**1/603 (0.17%)**
Peripheral Arterial Occlusive Disease * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**1/353 (0.28%)**	**0/603 (0.00%)**
Phlebitis * 1					
# participants affected / at risk	**0/1153 (0.00%)**	**1/307 (0.33%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**
Thrombosis * 1					
# participants affected / at risk	**1/1153 (0.09%)**	**0/307 (0.00%)**	**0/1046 (0.00%)**	**0/353 (0.00%)**	**0/603 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MEDDRA 11.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Only Treatment-Emergent Adverse Events are presented in the following sections, called as Frequent Adverse Events and Serious Adverse Events

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo	One placebo tablet twice daily for 6 months.
Riva 5 mg Total Daily Dose (TDD)	Rivaroxaban 5 mg (2.5 mg twice a day or 5 mg once daily) for 6 months.
Riva 10 mg TDD	Rivaroxaban 10 mg (5 mg twice a day or 10 mg once daily) for 6 months.
Riva 15 mg TDD	Rivaroxaban 15 mg (7.5 mg twice a day or 15 mg once daily) for 6 months.
Riva 20 mg TDD	Rivaroxaban 20 mg (10 mg twice a day or 20 mg once daily) for 6 months.

Other Adverse Events

	Placebo	Riva 5 mg Total Daily Dose (TDD)	Riva 10 mg TDD	Riva 15 mg TDD	Riva 20 mg TDD
Total, other (not including serious) adverse events					
# participants affected / at risk	**223/1153 (19.34%)**	**67/307 (21.82%)**	**293/1046 (28.01%)**	**108/353 (30.59%)**	**148/603 (24.54%)**

Cardiac disorders					
Angina Pectoris * 1					
# participants affected / at risk	**44/1153 (3.82%)**	**16/307 (5.21%)**	**43/1046 (4.11%)**	**8/353 (2.27%)**	**22/603 (3.65%)**
Gastrointestinal disorders					
Gingival Bleeding * 1					
# participants affected / at risk	**13/1153 (1.13%)**	**4/307 (1.30%)**	**47/1046 (4.49%)**	**32/353 (9.07%)**	**33/603 (5.47%)**
General disorders					
Chest Pain * 1					
# participants affected / at risk	**91/1153 (7.89%)**	**26/307 (8.47%)**	**99/1046 (9.46%)**	**31/353 (8.78%)**	**48/603 (7.96%)**
Injury, poisoning and procedural complications					
Contusion * 1					
# participants affected / at risk	**33/1153 (2.86%)**	**8/307 (2.61%)**	**40/1046 (3.82%)**	**18/353 (5.10%)**	**31/603 (5.14%)**
Nervous system disorders					
Dizziness * 1					
# participants affected / at risk	**47/1153 (4.08%)**	**16/307 (5.21%)**	**32/1046 (3.06%)**	**9/353 (2.55%)**	**18/603 (2.99%)**
Respiratory, thoracic and mediastinal disorders					
Epistaxis * 1					
# participants affected / at risk	**24/1153 (2.08%)**	**11/307 (3.58%)**	**89/1046 (8.51%)**	**44/353 (12.46%)**	**46/603 (7.63%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MEDDRA 11.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

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.
The agreement is: ☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can

☐ embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

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Publications of Results:

Mega JL, Braunwald E, Mohanavelu S, Burton P, Poulter R, Misselwitz F, Hricak V, Barnathan ES, Bordes P, Witkowski A, Markov V, Oppenheimer L, Gibson CM; ATLAS ACS-TIMI 46 study group. Rivaroxaban versus placebo in patients with acute coronary syndromes (ATLAS ACS-TIMI 46): a randomised, double-blind, phase II trial. Lancet. 2009 Jul 4;374(9683):29-38. doi: 10.1016/S0140-6736(09)60738-8. Epub 2009 Jun 17.

Responsible Party:	VP FRANCHISE MED LDR, Johnson & Johnson Pharmaceutical Research and Development, L.L.C.
ClinicalTrials.gov Identifier:	NCT00402597 History of Changes
Obsolete Identifiers:	NCT01151332
Other Study ID Numbers:	CR013417 **39039039ACS2001**
Study First Received:	November 21, 2006
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Last Updated:	September 28, 2012
Health Authority:	United States: Food and Drug Administration

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