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<b>Study No.:</b> AR2103413
<b>Title:</b> An International Randomized Study Evaluating the Efficacy and Safety of Fondaparinux Sodium Versus Control Therapy in a Broad Range Of Subjects With ST Segment Elevation Acute Myocardial Infarction.
<b>Rationale:</b> ST-segment elevation myocardial infarction (STEMI) along with unstable angina (UA) and non-ST-segment elevation myocardial infarction (NSTEMI) refer to a range of acute myocardial ischemic states collectively referred to as acute coronary syndromes (ACS). The common pathophysiology underlying these events relates to sudden rupture of an existing atheromatous plaque, which exposes a thrombogenic surface causing platelet activation and thrombus formation. In turn, this can lead to partial or total occlusion of the coronary arteries. Acute myocardial infarction (AMI) presenting with ST-segment elevation on the electrocardiogram (ECG) is the consequence of interrupted myocardial perfusion supplied by a totally occluded coronary artery. In STEMI, rapid restoration of blood flow in the obstructed artery is critical to avoid significant irreversible loss of myocardium. Despite currently available therapies and interventions, subjects with STEMI remain at significant risk of death and cardiac events. Improvements in therapy should aim to further reduce vascular events without increasing bleeding or alternatively be similarly effective but better tolerated. Results from four Phase II studies evaluating fondaparinux in coronary artery disease supported continued investigation in this study.
<b>Phase:</b> III
<b>Study Period:</b> 22 August 2003 – 04 January 2006
<b>Study Design:</b> Randomized, double-blind, parallel group, controlled trial
<b>Centers:</b> 447 centers in 42 countries and coordinated by the Canadian Cardiovascular Collaboration Project Office (CCCPO) at the Population Health Research Institute at McMaster University, Hamilton, Canada.
<b>Indication:</b> STEMI treatment
<p><b>Treatment:</b> Subjects were randomized to receive fondaparinux or control treatment based on the reperfusion strategy selected by the investigator prior to randomization. Eligible subjects were allocated to one of the following strata based on their indication for UFH or not, and randomized as follows:</p> <ul style="list-style-type: none"> <li>• Stratum 1 - no indication for UFH therapy: Subjects were randomized to receive either fondaparinux* subcutaneously (s.c.) or placebo* s.c. for up to 8 days or hospital discharge, whichever was earlier.</li> <li>• Stratum 2 - indication for UFH therapy: Subjects were randomized to receive either fondaparinux* s.c. for up to 8 days or hospital discharge, whichever was earlier, or i.v. UFH for 24 to 48 hours (or single bolus injection in case of primary PCI). Fondaparinux or UFH were administered using a double-dummy technique.</li> </ul> <p>(*Note: First dose of fondaparinux or fondaparinux-placebo was administered as an i.v. bolus).</p> <p>In case of elective or rescue PCI after randomization, the blinded study drug was stopped and the procedure was performed as per local practice with open-label UFH. The use of GPIIb/IIIa inhibitor was left to the investigator's discretion.</p> <p>For subjects undergoing coronary artery bypass graft (CABG) surgery during the treatment period, study drug administration was to be temporarily interrupted 24 hours pre-operatively and restarted 48 hours post-operatively, if possible.</p> <p>Using a 2x2 factorial design, consenting non-diabetic subjects were further randomized to receive glucose-potassium-insulin (GIK) or control (as an adjunct to fondaparinux/comparator) for 24 hours. This component of the study was terminated through a protocol amendment, dated 16 December 2004, after 2766 (22.9%) subjects were included.</p>
<p><b>Objectives:</b> The primary objective was to evaluate whether fondaparinux was superior to control (unfractionated heparin [UFH] or placebo) in preventing death or recurrent myocardial infarction (re-MI) up to Day 30 in subjects with STEMI.</p> <p>Secondary objectives were:</p> <ul style="list-style-type: none"> <li>• To evaluate whether fondaparinux was superior to control in preventing death or re-MI at Day 9, Day 90, and Day 180.</li> <li>• To evaluate whether fondaparinux was superior to control in preventing death, re-MI or refractory ischemia up to Day 30.</li> <li>• To evaluate whether fondaparinux was superior to control in reducing severe hemorrhage events (modified TIMI criteria) up to Day 9.</li> </ul>

<p><b>Primary Outcome/Efficacy Variable:</b> Time to first occurrence of any component of the composite of death (all-cause mortality) or adjudicated recurrent MI up to and including Day 30.</p>
<p><b>Primary Outcome/Safety Variable:</b> The primary safety outcome was time to first occurrence of adjudicated severe hemorrhage (modified TIMI criteria) up to and including Day 9.</p>
<p><b>Secondary Outcome/Efficacy Variable(s):</b></p> <ul style="list-style-type: none"> <li>• Time to first occurrence of death or recurrent MI (as adjudicated) up to and including Day 9, 90, and 180.</li> <li>• Time to first occurrence of death, recurrent MI or refractory ischemia (as adjudicated) up to and including Day 9, 30, 90, and 180.</li> <li>• Time to first occurrence of death or recurrent MI (as adjudicated) taken separately up to and including Day 9, 90, and 180.</li> </ul>
<p><b>Statistical Methods:</b> The sample size of 6,000 subjects per treatment group was sufficient to provide 84% power to detect a 15% relative reduction in the hazard ratio with a two sided 5% significance level, assuming a control event rate of 12%. The primary efficacy variable was analyzed using a stratified Cox proportional hazards model, stratified by indication of UFH. The objective of superiority was addressed by the following hypothesis:</p> <ol style="list-style-type: none"> <li>1. <math>H_0</math>: Hazard ratio of fondaparinux versus control (up to Day 30) = 1</li> <li>2. <math>H_1</math>: Hazard ratio of fondaparinux versus control (up to Day 30) &lt; 1.</li> </ol> <p>Fondaparinux was considered superior to control treatment if the upper limit of the two-sided 95% confidence interval of the hazard ratio did not exceed 1 (corresponding to a p-value of 0.05).</p> <p>All subjects randomized into the study (All Randomized Population) were analysed in all safety and efficacy analyses. In addition, safety analyses were carried out according to the treatment that subjects actually received (As Treated Population). The primary safety outcome, the first occurrence of severe hemorrhage (modified TIMI criteria), was analyzed up to Day 9 using a stratified Cox proportional hazards model, stratified by indication of UFH.</p>
<p><b>Study Population:</b> A broad range of subjects presenting with signs and symptoms of acute myocardial infarction (AMI) with definite ECG changes indicating STEMI, and able to be randomized within 12 hours of symptom onset were deemed eligible for this study. Subjects included those undergoing reperfusion for the index event including primary percutaneous coronary intervention (PCI) or thrombolysis with one of several thrombolytic regimens (streptokinase, urokinase, alteplase, reteplase, tenecteplase), as well as those subjects not eligible for reperfusion-therapy (e.g., late presentation or contra-indication to reperfusion-therapy).</p> <p>The key exclusion criteria were: Subjects with severe renal insufficiency (i.e., serum creatinine <math>\geq 3</math>mg/dL or <math>265 \mu\text{mol/L}</math>) or who had had low molecular weight heparin (LMWH) or <math>&gt;5000</math>IU UFH administered prior to randomization, or had undergone pre-randomization revascularization (PCI) for the index event or pre-randomization rescue PCI.</p>

	Overall		Stratum 1 No indication for UFH		Stratum 2 Indication for UFH	
	Fonda	Control	Fonda	Placebo	Fonda	UFH
<b>Number of Subjects</b>						
Planned N	6000	6000	--	--	--	--
Randomized, N	6036 (100)	6056 (100)	2823 (100)	2835 (100)	3213 (100)	3221 (100)
Not Treated, n (%)	83 (1.4)	108 (1.8)	19 (0.7)	13 (0.5)	64 (2.0)	95 (2.9)
Treated, n (%)	5953 (98.6)	5948 (98.2)	2804 (99.3)	2822 (99.5)	3149 (98.0)	3126 (97.1)
As Treated (Safety) Population, n (%)	5954 (98.6)	5947 (98.2)	2808 (99.5)	2818 (99.4)	3146 (97.9)	3129 (97.1)
Completed Treatment, n(%)	5455 (91.6)	5610 (94.3)	2614 (93.2)	2639 (93.5)	2841 (90.2)	2971 (95.0)
Total number of Subjects Withdrawn from Treatment	497 (8.3)	279 (4.7)	189 (6.7)	183 (6.5)	308 (9.8)	96 (3.1)
Withdrawn due to bleeding event	83 (1.4)	38 (0.6)	33 (1.2)	25 (0.9)	50 (1.6)	13 (0.4)
Withdrawn due to other SAEs	30 (0.5)	27 (0.4)	12 (0.4)	17 (0.6)	18 (0.6)	10 (0.3)
Withdrawn for Other Reasons	384 (6.4)	214 (3.5)	144 (5.1)	141 (5.0)	240 (7.5)	73 (2.3)
<b>Demographics</b>						
N (All Randomized)	6036	6056	2823	2835	3213	3221
Females: Males	1641:4393	1698:4353	787:2035	807:2028	854:2358	891:2325
Mean Age , years (SD)	61.6 (12.26)	61.5 (12.20)	61.0 (12.35)	61.2 (12.51)	62.2 (12.17)	61.7 (11.91)
European, n (%)	3803 (63.0)	3794 (62.6)	1339 (47.4)	1332 (47.0)	2464 (76.7)	2462 (76.4)
<b>Weight (kg)</b>						
Median (min-max)	75.0 (30-150)	75.0 (34-145)	72.0 (30-132)	72.0 (34-145)	75.4 (30-150)	75.3 (34-145)
<50 kg	132 (2.2)	100 (1.7)	81 (2.9)	69 (2.4)	51 (1.6)	82 (1.3)
≥50 - ≤100 kg	5512 (91.3)	5545 (91.6)	2623 (92.9)	2629 (92.7)	2889 (89.9)	5805 (90.2)
>100 kg	388 (6.4)	401 (6.6)	118 (4.2)	132 (4.7)	270 (8.4)	539 (8.4)
Missing	4 (<0.1)	10 (0.2)	1 (<0.1)	5 (0.2)	3 (<0.1)	8 (0.1)
<b>Creatinine Clearance (mL/min)</b>						
<20mL/min	24 (0.4)	24 (0.4)	11 (0.4)	18 (0.6)	13 (0.4)	6 (0.2)
≥20 - <30mL/min	109 (1.8)	105 (1.7)	54 (1.9)	54 (1.9)	55 (1.7)	51 (1.6)
≥30 - <50mL/min	812 (13.5)	839 (13.9)	408 (14.5)	426 (15.0)	404 (12.6)	413 (12.8)
≥50 - <80mL/min	2299 (38.1)	2250 (37.2)	1163 (41.2)	1143 (40.3)	1136 (35.4)	1107 (34.4)
≥ 80mL/min	2704 (44.8)	2752 (45.4)	1153 (40.8)	1156 (40.8)	1551 (48.3)	1596 (49.5)
Missing	88 (1.5)	86 (1.4)	34 (1.2)	38 (1.3)	54 (1.7)	48 (1.5)
<b>Primary Efficacy Result (All Randomized Population)</b>						
<b>Adjudicated Death/Recurrent MI Up to Day 30</b>						
Events, n%	584 (9.7)	675 (11.1)	318 (11.3)	396 (14.0)	266 (8.3)	279 (8.7)
Adjusted Hazard Ratio	0.86		0.80		0.94	
95% CI; p-value	(0.77, 0.96); 0.008		(0.69, 0.93); 0.003		(0.79, 1.11); 0.460	
<b>Primary Safety Result (All Randomized Population)</b>						
<b>Adjudicated Severe Hemorrhage (modified TIMI criteria) up to and Including Day 9</b>						
Events, n (%)	69 (1.1)	85 (1.4)	28 (1.0)	46 (1.6)	41 (1.3)	39 (1.2)
Adjusted Hazard Ratio	0.81		0.60		1.06	
95% CI; p-value	(0.59, 1.12); 0.199		(0.38, 0.97); 0.036		(0.68, 1.64); 0.801	

<b>Secondary Efficacy Outcome Variable(s):</b>						
	<b>Overall</b>		<b>Stratum 1 No indication for UFH</b>		<b>Stratum 2 Indication for UFH</b>	
	<b>Fonda N=6036</b>	<b>Control N=6056</b>	<b>Fonda N=2823</b>	<b>Placebo N=2835</b>	<b>Fonda N=3213</b>	<b>UFH N=3221</b>
<b>Adjudicated Death/Recurrent MI Up to Day 9</b>						
Events, n (%)	443 (7.3)	536 (8.9)	240 (8.5)	314 (11.1)	203 (6.3)	222 (6.9)
Hazard Ratio, (95% CI) Fonda vs Control	0.82, (0.73, 0.94)		0.76, (0.64, 0.90)		0.91, (0.75, 1.10)	
<b>Adjudicated Death/Recurrent MI Up to Day 90</b>						
Events, n (%)	683 (11.3)	796 (13.1)	369 (13.1)	441 (15.6)	314 (9.8)	355 (11.0)
Hazard Ratio, (95% CI)	0.85, (0.77, 0.94)		0.83, (0.72, 0.95)		0.87, (0.75, 1.02)	
<b>Adjudicated Death/Recurrent MI Up to Day 180</b>						
Events, n (%)	756 (12.5)	855 (14.1)	414 (14.7)	469 (16.5)	342 (10.6)	386 (12.0)
Hazard Ratio, (95% CI)	0.88, (0.79, 0.97)		0.87, (0.77, 1.00)		0.87, (0.75, 1.01)	
<b>Adjudicated Death/Recurrent MI/Refractory Ischemia Up to Day 9</b>						
Events, n (%)	466 (7.7)	559 (9.2)	253 (9.0)	326 (11.5)	213 (6.6)	233 (7.2)
Hazard Ratio, (95% CI)	0.83, (0.74, 0.94)		0.77, (0.65, 0.91)		0.91, (0.76, 1.10)	
<b>Adjudicated Death/Recurrent MI/Refractory Ischemia Up to Day 30</b>						
Events, n (%)	610 (10.1)	700 (11.6)	332 (11.8)	408 (14.4)	278 (8.7)	292 (9.1)
Hazard Ratio, (95% CI)	0.87, (0.78, 0.97)		0.81, (0.70, 0.94)		0.94, (0.80, 1.11)	
<b>Adjudicated Death/Recurrent MI/ Refractory Ischemia Up to Day 90</b>						
Events, n (%)	711 (11.8)	821 (13.6)	383 (13.6)	453 (16.0)	328 (10.2)	368 (11.4)
Hazard Ratio, (95% CI)	0.86, (0.78, 0.95)		0.84, (0.73, 0.96)		0.88, (0.76, 1.02)	
<b>Adjudicated Death/Recurrent MI/ Refractory Ischemia Up to Day 180</b>						
Number of Events, n (%)	784 (13.0)	881 (14.5)	427 (15.1)	481 (17.0)	357 (11.1)	400 (12.4)
Hazard Ratio, (95% CI)	0.88, (0.80, 0.97)		0.88, (0.77, 1.00)		0.88, (0.76, 1.02)	
<b>Adjudicated Death Up to Day 9</b>						
Events, n (%)	368 (6.1)	426 (7.0)	202 (7.2)	252 (8.9)	166 (5.2)	174 (5.4)
Hazard Ratio, (95% CI)	0.86, (0.75, 0.99)		0.80, (0.66, 0.96)		0.95, (0.77, 1.17)	
<b>Adjudicated Death Up to Day 30</b>						
Events, n (%)	470 (7.8)	541 (8.9)	257 (9.1)	321 (11.3)	213 (6.6)	220 (6.8)
Hazard Ratio, (95% CI)	0.87, (0.77, 0.98)		0.80, (0.68, 0.94)		0.95, (0.79, 1.15)	
<b>Adjudicated Death Up to Day 90</b>						
Events, n (%)	545 (9.0)	634 (10.5)	301 (10.7)	354 (12.5)	244 (7.6)	280 (8.7)
Hazard Ratio, (95% CI)	0.86, (0.76, 0.96)		0.85, (0.73, 0.99)		0.86, (0.72, 1.02)	
<b>Adjudicated Death Up to Day 180</b>						
Events, n (%)	599 (9.9)	675 (11.1)	336 (11.9)	375 (13.2)	263 (8.2)	300 (9.3)
Hazard Ratio, (95% CI)	0.88, (0.79, 0.99)		0.89, (0.77, 1.04)		0.87, (0.73, 1.02)	
<b>Recurrent MI Up to Day 9</b>						
Events, n (%)	91 (1.5)	134 (2.2)	49 (1.7)	72 (2.5)	42 (1.3)	62 (1.9)
Hazard Ratio, (95% CI)	0.68, (0.52, 0.88)		0.67, (0.47, 0.97)		0.68, (0.46, 1.01)	
<b>Recurrent MI Up to Day 30</b>						
Events, n (%)	141 (2.3)	172 (2.8)	74 (2.6)	92 (3.2)	67 (2.1)	80 (2.5)
Hazard Ratio, (95% CI)	0.81, (0.65, 1.02)		0.79, (0.58, 1.07)		0.83, (0.60, 1.15)	
<b>Recurrent MI Up to Day 90</b>						
Events, n (%)	174 (2.9)	217 (3.6)	88 (3.1)	109 (3.8)	86 (2.7)	108 (3.4)
Hazard Ratio, (95% CI)	0.79, (0.65, 0.97)		0.79, (0.60, 1.05)		0.79, (0.59, 1.04)	
<b>Recurrent MI Up to Day 180</b>						
Events, n (%)	199 (3.3)	242 (4.0)	101 (3.6)	117 (4.1)	98 (3.1)	125 (3.9)
Hazard Ratio, (95% CI)	0.81, (0.67, 0.98)		0.85, (0.65, 1.10)		0.77, (0.59, 1.01)	

**Safety Results:** An 'on-therapy' adverse event (AE) was defined as any AE with onset between randomization to 2 days after the last dose of study drug. An 'on-therapy' serious AE (SAE) was defined as any SAE with onset between randomization to 2 days after the last dose of study drug. Safety analyses were based on the "as treated" population that reflects subjects receiving study drug and accounts for the medication actually taken in the event of mistaken allocation of randomized medication. Events that were recorded as efficacy outcomes (e.g., death or recurrent MI) were not to have been recorded as AEs. However, some were. Only those that were recorded by the investigator as an (S)AE are included in the Safety Results. Bleeding events were to be reported both as part of the bleeding safety endpoints and as Aes if they met the individual definitions.

	Overall		Stratum 1 No indication for UFH		Stratum 2 Indication for UFH	
	Fonda N=5954	Control N=5947	Fonda N=2808	Placebo N=2818	Fonda N=3146	UFH N=3129
Subject with any AE, n (%)	1933 (32)	1959 (33)	922 (33)	954 (34)	1011 (32)	1005 (32)
<b>10 Most Frequent AEs in each group, n (%)</b>						
Pyrexia	189 (3)	200 (3)	119 (4)	125 (4)	70 (2)	75 (2)
Atrial fibrillation	164 (3)	126 (2)	69 (2)	57 (2)	95 (3)	69 (2)
Chest pain	108 (2)	79 (1)	50 (2)	42 (1)	28 (2)	37 (1)
Headache	105 (2)	118 (2)	60 (2)	63 (2)	45 (1)	55 (2)
Ventricular tachycardia	76 (1)	81 (1)	26 (<1)	29 (1)	50 (2)	52 (2)
Hypotension	75 (1)	72 (1)	36 (1)	35 (1)	39 (1)	37 (1)
Vomiting	74 (1)	74 (1)	47 (2)	42 (1)	27 (<1)	32 (1)
Pneumonia	59 (<1)	57 (<1)	34 (1)	32 (1)	25 (<1)	25 (<1)
Diabetes Mellitus	57 (<1)	60 (1)	23 (<1)	19 (<1)	34 (1)	41 (1)
Pericarditis	50 (<1)	53 (<1)	22 (<1)	21 (<1)	28 (<1)	32 (1)
<b>Serious Adverse Events - On Therapy – (As Treated Population)</b>						
<b>n (%) [n considered by the investigator to be related to study medication]</b>						
	Overall		Stratum 1 No indication for UFH		Stratum 2 Indication for UFH	
	Fond	Control	Fonda	Placebo	Fond	UFH
Subjects with any SAE, includes fatal and non-fatal n (%)	188 (3) [67]	216 (4) [52]	73 (3) [20]	92 (3) [14]	115 (4) [47]	124 (4) [38]
Pericardial hemorrhage	28 (<1) [7]	42 (<1) [3]	17 (<1) [2]	27 (<1) [1]	11 (<1) [5]	15 (<1) [2]
Gastrointestinal hemorrhage	11 (<1) [11]	14 (<1) [11]	3 (<1) [3]	7 (<1) [5]	8 (<1) [8]	7 (<1) [6]
Puncture site hemorrhage	11 (<1) [7]	12 (<1) [7]	1 (<1) [1]	0	10 (<1) [6]	12 (<1) [7]
Coronary artery thrombosis	10 (<1) [6]	9 (<1) [6]	0	1 (<1) [1]	10 (<1) [6]	8 (<1) [5]
Renal failure acute	9 (<1) [2]	12 (<1) [1]	4 (<1) [1]	6 (<1)	5 (<1) [1]	6 (<1) [1]
Hemorrhagic stroke	6 (<1) [5]	7 (<1) [5]	3 (<1) [2]	3 (<1) [2]	3 (<1) [3]	4 (<1) [3]
Pneumonia	7 (<1)	12 (<1)	3 (<1)	4 (<1)	4 (<1)	8 (<1)
Renal failure	2 (<1)	5 (<1)	0	1 (<1)	2 (<1)	4 (<1)
Hemorrhage intracranial	3 (<1) [3]	2 (<1) [1]	2 (<1) [2]	2 (<1) [1]	1 (<1) [1]	0
Gastric ulcer hemorrhage	3 (<1) [3]	2 (<1)	1 (<1) [1]	1 (<1)	2 (<1) [2]	1 (<1)
Anemia	3 (<1)	1 (<1)	1 (<1)	0	2 (<1)	1 (<1)
Vascular pseudoaneurysm	3 (<1) [1]	3 (<1) [1]	0	0	3 (<1) [1]	3 (<1) [1]
Interventricular septum rupture	2 (<1)	3 (<1)	0	1 (<1)	2 (<1)	2 (<1)
Retroperitoneal hemorrhage	2 (<1) [1]	3 (<1) [2]	1 (<1)	2 (<1) [1]	1 (<1) [1]	1 (<1) [1]
Hemorrhage	2 (<1) [1]	2 (<1) [1]	1 (<1) [1]	1 (<1) [1]	1 (<1)	1 (<1)
Hemoglobin decreased	2 (<1) [1]	2 (<1) [2]	2 (<1) [1]	1 (<1) [1]	0	1 (<1) [1]
Cerebrovascular accident	2 (<1) [1]	1 (<1) [1]	2 (<1) [1]	1 (<1) [1]	0	0

Sepsis	2 (<1)	2 (<1)	2 (<1)	1 (<1)	0	1 (<1)
Catheter related complication	2 (<1) [1]	2 (<1) [2]	0	0	2 (<1) [1]	2 (<1) [2]
Pyrexia	2 (<1)	1 (<1)	0	0	2 (<1)	1 (<1)
Hematoma	2 (<1)	1 (<1)	0	0	2 (<1)	0
Hemoptysis	2 (<1) [2]	0	1 (<1) [1]		1 (<1) [1]	0
Lung neoplasm malignant	2 (<1)	0	1 (<1)	0	1 (<1)	0
Hemorrhoidal hemorrhage	2 (<1)	0	0	0	2 (<1)	0
Septic shock	2 (<1)	0	1 (<1)	0	1 (<1)	0
Pulmonary embolism	1 (<1)	5 (<1)	1 (<1)	3 (<1)	0	2 (<1)
Cerebral hemorrhage	1 (<1) [1]	2 (<1)	1 (<1) [1]	1 (<1)	0	1 (<1)
Gastric hemorrhage	1 (<1)	1 (<1) [1]	1 (<1)	0	0	1 (<1) [1]
Hematemesis	1 (<1)	1 (<1) [1]	1 (<1)	0	0	1 (<1) [1]
Brochopneumonia	1 (<1)	2 (<1)	0	1 (<1)	1 (<1)	1 (<1)
Lung infection	1 (<1)	2 (<1)	0	2 (<1)	1 (<1)	0
Dressler's syndrome	1 (<1)	1 (<1)	1 (<1)	0	0	1 (<1)
Pericardial effusion	1 (<1)	1 (<1)	0	0	1 (<1)	1 (<1)
Abdominal pain	1 (<1)	0	1 (<1)	0	0	0
Hematuria	1 (<1)	1 (<1) [1]	1 (<1)	1 (<1) [1]	0	0
Peripheral embolism	1 (<1)	1 (<1) [1]	1 (<1)	0	0	1 (<1) [1]
Hypotension	1 (<1)	2 (<1) [1]	0	0	1 (<1)	2 (<1) [1]
Embolism	1 (<1)	1 (<1)	0	0	1 (<1)	0
Cerebral infarction	1 (<1)	1 (<1)	0	0	1 (<1)	1 (<1)
Cholecystitis acute	1 (<1)	1 (<1)	1 (<1)	1 (<1)	0	0
Thrombocytopenia	1 (<1) [1]	1 (<1) [1]	0	0	1 (<1) [1]	1 (<1) [1]
Duodenal ulcer hemorrhage	1 (<1) [1]	0	0	0	1 (<1) [1]	0
Hemorrhoids	1 (<1) [1]	0	0	0	1 (<1) [1]	0
Intestinal ischemia	1 (<1)	0	0	0	1 (<1)	0
Intestinal perforation	1 (<1)	0	1 (<1)	0	0	0
Upper GI hemorrhage	1 (<1) [1]	0	0	0	1 (<1) [1]	0
Clostridium Difficile sepsis	1 (<1)	0	0	0	1 (<1)	0
HIV infection	1 (<1)	0	0	0	0	1 (<1)
Lower respiratory infection	1 (<1)	0	1 (<1)	0	0	0
Pneumonia hemophilus	1 (<1)	0	0	0	1 (<1)	0
Adams-Stokes syndrome	1 (<1)	0	0	0	1 (<1)	0
Coronary artery dissection	1 (<1)	0	0	0	1 (<1)	0
Coronary artery stenosis	1 (<1)	0	1 (<1)	0	0	0
Intracardiac thrombus	1 (<1)	0	0	0	1 (<1)	0
Myocardial rupture	1 (<1)	0	1 (<1)	0	0	0
Typhoid fever	1 (<1)	0	1 (<1)	0	0	0
Viral infection	1 (<1)	0	0	0	1 (<1)	0
Viral upper respiratory infection	1 (<1)	0	0	0	1 (<1)	0
Cerebral venous thrombosis	1 (<1)	0	0	0	1 (<1)	0
Encephalopathy	1 (<1)	0	0	0	1 (<1)	0
Hypertension encephalopathy	1 (<1)	0	1 (<1)	0	0	0
Neurological symptom	1 (<1)	0	0	0	1 (<1)	0
Application site bleeding	1 (<1) [1]	0	0	0	1 (<1) [1]	0
Multi-Organ disorder	1 (<1)	0	1 (<1)	0	0	1 (<1)
Nephroapthy toxic	1 (<1)	0	0	0	1 (<1)	0
Aneurysm	1 (<1) [1]	0	0	0	1 (<1) [1]	0
Arterial rupture	1 (<1)	0	0	0	1 (<1)	0

Atherosclerosis Obliterans	1 (<1)	0	1 (<1)	0	0	0
Hemorrhoids	1 (<1)	0	0	0	1 (<1)	0
Ischemia	1 (<1)	0	1 (<1)	0	0	0
Hemothorax	1 (<1) [1]	0	1 (<1) [1]	0	0	0
Concussion	1 (<1)	0	0	0	1 (<1)	0
Operative hemorrhage	1 (<1) [1]	0	0	0	1 (<1) [1]	0
Scrotal hematoma	1 (<1)	0	0	0	1 (<1)	0
Subcutaneous hematoma	1 (<1)	0	1 (<1)	0	0	0
Polycythemia vera	1 (<1)	1 (<1)	1 (<1)	0	0	1 (<1)
Gastric cancer	1 (<1)	0	0	0	1 (<1)	0
Hypercoagulation	1 (<1)	0	0	0	1 (<1)	0
Diabetes mellitus	1 (<1)	1 (<1)	0	1 (<1)	1 (<1)	0
Diabetic foot	1 (<1)	0	1 (<1)	0	0	0
Hyperglycemia	1 (<1)	0	0	0	1 (<1)	0
Pulmonary hemorrhage	1 (<1)	1 (<1) [1]	0	0	1 (<1)	1 (<1) [1]
Intra-abdominal hemorrhage	1 (<1) [1]	0	1 (<1) [1]	0	0	0
Esophageal varices hemorrhage	1 (<1) [1]	0	0	0	1 (<1) [1]	0
Peptic ulcer hemorrhage	1 (<1) [1]	0	0	0	1 (<1) [1]	0
Retroperitoneal hematoma	1 (<1)	0	0	0	1 (<1)	0
Interstitial lung disease	1 (<1)	0	0	0	1 (<1)	0
Pharyngeal edema	1 (<1) [1]	0	0	0	1 (<1) [1]	0
Pleura hemorrhage	1 (<1)	0	1 (<1)	0	0	0
Insulin resistant diabetes	1 (<1)	0	0	0	1 (<1)	0
Cholelithiasis	1 (<1)	0	1 (<1)	0	0	0
Hepatic failure	1 (<1)	0	0	0	1 (<1)	0
Blood creatinine increased	1 (<1)	0	1 (<1)	0	0	0
Ventricular septal defect	1 (<1)	2 (<1)	0	0	1 (<1)	2 (<1)
Anaphylactic shock	1 (<1)	0	1 (<1)	0	0	0
Delirium tremens	1 (<1)	0	0	0	1 (<1)	0
Eye hemorrhage	1 (<1) [1]	0	0	0	1 (<1) [1]	0
Monarthritis	1 (<1)	0	1 (<1)	0	0	0
Prostatitis	1 (<1)	0	1 (<1)	0	0	0
Purpura	1 (<1) [1]	0	1 (<1) [1]	0	0	0
Post procedural hemorrhage	0	5 (<1) [1]	0	1 (<1)	0	4 (<1) [1]
Pericarditis	0	2 (<1)	0	1 (<1)	0	1 (<1)
Cardiac tamponade	0	2 (<1) [1]	0	0	0	2 (<1) [1]
Renal failure chronic	0	1 (<1)	0	0	0	1 (<1)
Pyelonephritis acute	0	1 (<1)	0	1 (<1)	0	0
Cardiac aneurysm	0	1 (<1)	0	0	0	1 (<1)
Cardiac arrest	0	1 (<1)	0	1 (<1)	0	0
Cardiac Pseudoaneurysm	0	1 (<1)	0	0	0	1 (<1)
Acute abdomen	0	1 (<1)	0	1 (<1)	0	0
Diarrhea	0	1 (<1)	0	0	0	1 (<1)
Enteritis	0	1 (<1)	0	1 (<1)	0	0
Gingival bleeding	0	1 (<1)	0	0	0	1 (<1)
Urinary tract infection	0	2 (<1)	0	1 (<1)	0	1 (<1)
Bronchitis	0	1 (<1)	0	0	0	1 (<1)
Gastroenteritis	0	2 (<1)	0	1 (<1)	0	1 (<1)
Respiratory tract infection	0	2 (<1)	0	2 (<1)	0	0
Subarachnoid hemorrhage	0	1 (<1) [1]	0	0	0	1 (<1) [1]
Drug toxicity	0	1 (<1)	0	0	0	1 (<1)
Deep vein thrombosis	0	1 (<1)	0	0	0	1 (<1)

Arteriosclerosis	0	1 (<1)	0	0	0	1 (<1)
Hemorrhagic transformation stroke	0	1 (<1)	0	1 (<1)	0	0
Convulsion	0	1 (<1)	0	0	0	1 (<1)
Aortic dissection	0	1 (<1)	0	1 (<1)	0	0
Thrombophlebitis	0	2 (<1)	0	0	0	2 (<1)
Pneumothorax	0	1 (<1)	0	0	0	1 (<1)
Coma	0	1 (<1)	0	0	0	1 (<1)
Psychotic disorder	0	1 (<1)	0	0	0	1 (<1)
Hyperparathyroidism	0	1 (<1)	0	1 (<1)	0	0
Anaphylactoid reaction	0	1 (<1)	0	1 (<1)	0	0
Acute psychosis	0	1 (<1)	0	1 (<1)	0	0
Delirium	0	1 (<1)	0	0	0	1 (<1)
Marfan's syndrome	0	1 (<1)	0	1 (<1)	0	0
Anaphylactic reaction	0	1 (<1)	0	1 (<1)	0	0
Cholecystitis	0	1 (<1)	0	0	0	1 (<1)
Dehydration	0	1 (<1)	0	0	0	1 (<1)
Diabetes mellitus inadequate control	0	1 (<1)	0	1 (<1)	0	0
Gastrointestinal stromal tumor	0	1 (<1)	0	0	0	1 (<1)
Hepatic neoplasm malignant	0	1 (<1)	0	1 (<1)	0	0
Pancreatic carcinoma metastatic	0	1 (<1)	0	1 (<1)	0	0
Thyroid gland cancer	0	1 (<1)	0	0	0	1 (<1)
Acute respiratory failure	0	1 (<1)	0	1 (<1)	0	0
Epistaxis	0	1 (<1) [1]	0	0	0	1 (<1) [1]
Reocclusion	0	1 (<1)	0	0	0	1 (<1)
Reperfusion injury	0	1 (<1)	0	0	0	1 (<1)
Peripheral vascular disorder	0	1 (<1)	0	1 (<1)	0	0
Venous thrombosis	0	1 (<1)	0	1 (<1)	0	0
Diabetic ketoacidosis	0	1 (<1)	0	0	0	1 (<1)
Brain neoplasm	0	1 (<1)	0	1 (<1)	0	0
Colon cancer	0	1 (<1)	0	1 (<1)	0	0
Subdural hematoma	0	1 (<1)	0	1 (<1)	0	0
Thrombosis in device	0	1 (<1)	0	1 (<1)	0	0
Traumatic hematoma	0	1 (<1)	0	1 (<1)	0	0
Urinary bladder rupture	0	1 (<1)	0	1 (<1)	0	0
Iron deficiency anemia	0	1 (<1)	0	1 (<1)	0	0
Leukemia	0	1 (<1)	0	0	0	1 (<1)
Multi-Organ failure	0	1 (<1)	0	0	0	0
Amputation	0	1 (<1)	0	0	0	1 (<1)

**Conclusion:**

See publication below.

**Publication:**

**The OASIS 6 Trial Group.** Effects of Fondaparinux on Mortality and Reinfarction in Patients with Acute ST Segment Elevation Myocardial Infarction. The OASIS 6 Randomized Trial. JAMA. 2006;295:1519-30.

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