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Study No.: AR1103420
Title: An International, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Fondaparinux versus Enoxaparin in the Acute Treatment of Unstable Angina /Non ST-Segment Elevation MI Acute Coronary Syndromes
Rationale: Unstable angina (UA) and non-ST-segment elevation myocardial infarction (NSTEMI) are a major cause of emergency medical care and are responsible for more than 1.4 million hospitalizations each year in the United States alone. Despite currently available therapies and interventions, patients with UA/NSTEMI 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.
Phase: III
Study Period: 30 April 2003 – 12 Dec 2005
Study Design: Double-blind, double-dummy, parallel-group, controlled trial to compare the efficacy and safety of fondaparinux and enoxaparin in subjects with unstable angina (UA) / non-ST segment elevation myocardial infarction (NSTEMI).
Centres: 576 centers in 42 countries
Indication: UA/NSTEMI treatment
Treatment: Subjects were randomized to receive a subcutaneous (s.c.) injection of fondaparinux 2.5mg once daily (up to 8 days or hospital discharge, whichever was earlier) or weight-adjusted enoxaparin (1mg/kg) twice daily (2-8 days or until clinically stable, whichever was earlier), both administered in a double-blind double-dummy fashion. If creatinine clearance was between 20mL/min and 30mL/min, enoxaparin was dosed once-daily. Subjects undergoing percutaneous coronary interventions (PCI) during the treatment period also received in a blinded fashion a single preprocedural dose of either intravenous (i.v.) fondaparinux (fondaparinux subjects) or i.v. UFH (enoxaparin subjects). The i.v. dose of both fondaparinux and UFH was determined by an algorithm that was based on the time of administration of the previous s.c. dose of study drug and the planned use of i.v. GPIIb/IIIa inhibitors. Study drug was to be re-started after PCI, if possible. 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.
Objectives: The primary objective was to evaluate whether fondaparinux is at least as effective as or superior to enoxaparin in preventing death, myocardial infarction (MI), or refractory ischemia (RI) up to Day 9 in the acute treatment of subjects with UA/NSTEMI concurrently managed with standard medical therapy. Secondary objectives were: <ul style="list-style-type: none"> • To determine whether fondaparinux is superior to enoxaparin in reducing death and MI at Day 9. • To determine whether fondaparinux is superior to enoxaparin in reducing major bleeding events up to Day 9. • To determine if the relative effect on the primary endpoint, i.e., prevention of death, MI, or RI, is sustained at Day 14, Day 30, Day 90, and Day 180.
Primary Outcome/Efficacy Variable: The primary efficacy outcome was the first occurrence of any component of death, MI, or RI (as adjudicated) up to and including Day 9.
Primary Outcome/Safety Variable: The primary safety outcome was the first occurrence of adjudicated major bleeding up to and including Day 9.
Secondary Outcome/Efficacy Variable(s): <ul style="list-style-type: none"> • The first occurrence of death, MI, or RI (as adjudicated) up to and including Day 14, Day 30, Day 90, and Day 180. • The first occurrence of death or MI (as adjudicated) up to and including Day 9, Day 14, Day 30, Day 90, and Day 180. • The first occurrence of death, MI, or RI (as adjudicated) taken separately up to and including Day 9, Day 14, Day 30, Day 90, and Day 180.
Statistical Methods: The study was to be completed when 1414 subjects with primary events were observed. Based on an expected pooled event rate of approximately 7%, 20,000 subjects would be required, which would provide at least 85% power. Fondaparinux was to be considered non-inferior to enoxaparin if the upper limit of the two-sided 95% confidence interval (CI) of the hazard ratio did not exceed the 1.185 non-inferiority margin. In addition, if this upper limit did not exceed 1, fondaparinux was to be considered statistically superior to enoxaparin. The possible switch from non-inferiority testing to superiority testing would not introduce multiplicity testing due to the nature of this closed testing procedure. The primary efficacy and safety populations ("all randomized" population) included all

randomized subjects as originally allocated by the IVRS randomization system. The “as treated” population was also used for safety analyses; it included all randomized subjects who received at least 1 dose of study medication, and subjects were analyzed according to the treatment actually received. The primary efficacy analyses was also performed for the “per-protocol” population (which was the subset of “as treated” subjects without a protocol violation).

Study Population: A subject was eligible for inclusion in the study if the following criteria applied:

1. Presented or admitted to hospital with symptoms suspected to represent an acute coronary syndrome (ACS) (unstable angina or MI without persistent ST elevation), i.e., clinical history consistent with new onset, or a worsening pattern, of characteristic ischemic chest pain or ischemic symptoms occurring at rest or with minimal activity (lasting longer than 5 minutes or requiring sublingual nitroglycerin for relief of the pain).
2. Available to be randomized within 24 hours of the onset of the most recent episode of symptoms.
3. As per an amendment, presence of at least two of the three following additional criteria:
 - age ≥ 60 years;
 - Troponin T or I or creatine kinase MB (CK-MB) above the upper limit of normal for the local institution;
 - ECG changes compatible with ischemia, i.e., ST depression at least 1mm in 2 contiguous leads or T wave inversion >3 mm or any dynamic ST shift or transient ST elevation.

[Note: originally, age ≥ 60 years was not a requirement and subjects were to meet one of the two other criteria]

The key exclusion criteria were: Subjects with severe renal insufficiency (i.e. serum creatinine ≥ 3 mg/dL or $265\mu\text{mol/L}$), a contraindication to low molecular weight heparin, or who had already had a revascularization procedure performed for the qualifying event.

Number of Subjects:	Fondaparinux	Enoxaparin
Planned, N	10,000	10,000
Randomized, N	10,057	10,021
Not Treated, n (%)	71 (0.7%)	59 (0.6%)
Treated, n (%)	9986 (>99%)	9962 (>99%)
As Treated, n (%)	9979 (>99%)	9969 (>99%)
Per-protocol, n (%)	9862 (98.1%)	9840 (98.2%)
Completed, n (%)	8999 (90.2%)	8804 (88.4%)
Total Number Subjects Withdrawn, n (%)	987 (9.8%)	1158 (11.6%)
Withdrawn due to Bleeding Event, n (%)	159 (1.6%)	467 (4.7%)
Withdrawn due to Other Serious Adverse Events, n (%)	41 (0.4%)	33 (0.3%)
Withdrawn for other reasons n (%)	787 (7.8)	658 (6.6)
Demographics (all randomized population)	Fondaparinux	Enoxaparin
N	10,057	10,021
Females: Males	6231:3821	6148:3872
Mean Age, years (SD)	67.1 (10.75)	67.1 (11.02)
Ethnicity, n (%)		
European	8093 (80.5%)	8070 (80.5%)
Weight (kg)		
<50kg	151 (1.5%)	174 (1.7%)
≥ 50 - ≤ 100 kg	9315 (92.6%)	9256 (92.4%)
>100kg	591 (5.9%)	591 (5.9%)
Creatinine Clearance (mL/min)		
<20 mL/min	41 (0.4%)	44 (0.4%)
≥ 20 - <30 mL/min	241 (2.4%)	242 (2.4%)
≥ 30 - <50 mL/min	1660 (16.5%)	1720 (17.2%)
≥ 50 - <80 mL/min	4289 (42.6%)	4205 (42.0%)
≥ 80 mL/min	3785 (37.6%)	3768 (37.6%)
Missing	41 (0.4%)	42 (0.4%)
Primary Efficacy Results: (all randomized population)	Fondaparinux	Enoxaparin
Adjudicated Death/MI/RI Up to Day 9, n (%)	579 (5.8%)	574 (5.7%)
Adjusted Hazard Ratio (95% Confidence Interval)	1.01 (0.90,1.13)	
p-value (superiority)	0.923	
p-value (one-sided, non-inferiority)	0.003	

Primary Efficacy Results: (per-protocol population)	Fondaparinux	Enoxaparin
Adjudicated Death/MI/RI Up to Day 9, n (%)	566 (5.7%)	561 (5.7%)
Adjusted Hazard Ratio (95% Confidence Interval)	1.01 (0.90,1.13)	
p-value (superiority)	0.903	
Primary Safety Results: (all randomized population)	Fondaparinux	Enoxaparin
Adjudicated Major Bleeding, n (%)	214 (2.1%)	408 (4.1%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.52 (0.44, 0.61)	
p-value	<0.001	
Secondary Outcome Variable(s): (all randomized population)	Fondaparinux	Enoxaparin
Adjudicated Death/MI/RI Up to Day 14, n (%)	658 (6.5%)	701 (7.0%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.94 (0.84,1.04)	
Adjudicated Death/MI/RI Up to Day 30, n (%)	806 (8.0%)	865 (8.6%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.93 (0.84,1.02)	
Adjudicated Death/MI/RI Up to Day 90, n (%)	1044 (10.4%)	1112 (11.1%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.93 (0.86,1.02)	
Adjudicated Death/MI/RI Up to Day 180, n (%)	1223 (12.2%)	1309 (13.1%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.93 (0.86,1.00)	
Adjudicated Death/MI Up to Day 9, n (%)	409 (4.1%)	412 (4.1%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.99 (0.86,1.13)	
Adjudicated Death/MI Up to Day 14, n (%)	476 (4.7%)	524 (5.2%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.91 (0.80,1.02)	
Adjudicated Death/MI Up to Day 30, n (%)	619 (6.2%)	682 (6.8%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.90 (0.81,1.01)	
Adjudicated Death/MI Up to Day 90, n (%)	864 (8.6%)	930 (9.3%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.92 (0.84,1.01)	
Adjudicated Death/MI Up to Day 180, n (%)	1042 (10.4%)	1127 (11.2%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.92 (0.84,1.00)	
Adjudicated Death Up to Day 9, n (%)	177 (1.8%)	186 (1.9%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.95 (0.77,1.17)	
Adjudicated Death Up to Day 14, n (%)	211 (2.1%)	242 (2.4%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.87 (0.72,1.04)	
Adjudicated Death Up to Day 30, n (%)	295 (2.9%)	352 (3.5%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.83 (0.71,0.97)	
Adjudicated Death Up to Day 90, n (%)	460 (4.6%)	510 (5.1%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.90 (0.79,1.02)	
Adjudicated Death Up to Day 180, n (%)	574 (5.7%)	638 (6.4%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.89 (0.80,1.00)	
Adjudicated MI Up to Day 9, n (%)	263 (2.6%)	264 (2.6%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.99 (0.84,1.18)	
Adjudicated MI Up to Day 14, n (%)	305 (3.0%)	337 (3.4%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.90 (0.77,1.05)	
Adjudicated MI Up to Day 30, n (%)	387 (3.8%)	411 (4.1%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.94 (0.82,1.08)	
Adjudicated MI Up to Day 90, n (%)	509 (5.1%)	539 (5.4%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.94 (0.83,1.06)	
Adjudicated MI Up to Day 180, n (%)	606 (6.0%)	635 (6.3%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.95 (0.85,1.06)	
Adjudicated RI Up to Day 9, n (%)	194 (1.9%)	189 (1.9%)
Adjusted Hazard Ratio (95% Confidence Interval)	1.02 (0.84,1.25)	
Adjudicated RI Up to Day 14, n (%)	212 (2.1%)	212 (2.1%)
Adjusted Hazard Ratio (95% Confidence Interval)	1.00 (0.82,1.21)	
Adjudicated RI Up to Day 30, n (%)	221 (2.2%)	223 (2.2%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.99 (0.82,1.19)	
Adjudicated RI Up to Day 90, n (%)	227 (2.3%)	230 (2.3%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.98 (0.82,1.18)	

Adjudicated RI Up to Day 180, n (%)	233 (2.3%)	239 (2.4%)
Adjusted Hazard Ratio (95% Confidence Interval)	0.97 (0.81,1.16)	

Safety Results: An 'on-therapy' adverse event (AE) was defined as any AE with onset between the randomization call date and the last day of study medication, plus 2 days. An 'on-therapy' serious AE (SAE) was defined as any SAE with onset between the randomization call date and the last day of study medication, plus 2 days. 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, MI, RI) 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.

Most Frequent On-Therapy Adverse Events – As Treated Population, n (%)	Fondaparinux (N=9979)	Enoxaparin (N=9969)
Subjects with any AE(s), n (%)	2426 (24%)	2785 (28%)
10 Most Frequent AEs in Each Group, n (%)		
Headache	227 (2%)	226 (2%)
Chest pain	148 (1%)	147 (1%)
Atrial fibrillation	103 (1%)	124 (1%)
Pyrexia	96 (<1%)	110 (1%)
Urinary tract infection	84 (<1%)	77 (<1%)
Angina pectoris	68 (<1%)	43 (<1%)
Nausea	68 (<1%)	89 (<1%)
Pneumonia	64 (<1%)	67 (<1%)
Cough	60 (<1%)	53 (<1%)
Hematoma	57 (<1%)	79 (<1%)
Post-procedural hemorrhage	57 (<1%)	54 (<1%)
Hypotension	53 (<1%)	83 (<1%)
Vascular pseudoaneurysm	40 (<1%)	77 (<1%)
Puncture site hemorrhage	37 (<1%)	123 (1%)
Serious Adverse Events - On-Therapy – As Treated Population n (%) [n considered by the investigator to be related to study medication]		
	Fondaparinux (N=9979)	Enoxaparin (N=9969)
Subjects with any SAEs, includes fatal and non-fatal events		
Subjects with any SAE	360 (4%) [163]	520 (5%) [285]
Puncture site hemorrhage	35 (<1%) [29]	118 (<1%) [104]
Post procedural hemorrhage	34 (<1%) [20]	23 (<1%) [16]
Catheter related complication	34 (<1%) [27]	11 (<1%) [5]
Vascular pseudoaneurysm	22 (<1%) [12]	42 (<1%) [28]
Gastrointestinal hemorrhage	20 (<1%) [17]	24 (<1%) [24]
Coronary artery thrombosis	16 (<1%) [14]	5 (<1%) [4]
Pneumonia	12 (<1%)	19 (<1%)
Renal failure acute	11 (<1%)	15 (<1%)
Pericardial hemorrhage	8 (<1%) [2]	5 (<1%) [2]
Retroperitoneal hemorrhage	6 (<1%) [5]	20 (<1%) [16]
Respiratory failure	6 (<1%)	4 (<1%)
Hematuria	5 (<1%) [4]	7 (<1%) [7]
Thrombocytopenia	5 (<1%) [3]	7 (<1%) [4]
Renal failure	5 (<1%)	6 (<1%)
Pulmonary embolism	4 (<1%)	5 (<1%)
Cholecystitis acute	4 (<1%)	4 (<1%)
Hemorrhagic stroke	4 (<1%) [3]	1 (<1%) [1]
Sepsis	4 (<1%)	1 (<1%)
Coronary artery dissection	3 (<1%)	1 (<1%)
Diabetes mellitus inadequate control	3 (<1%)	1 (<1%)

Pericarditis	3 (<1%)	1 (<1%)
Anemia	2 (<1%) [1]	10 (<1%) [4]
Hematuria traumatic	2 (<1%) [1]	4 (<1%) [4]
Hemothorax	2 (<1%) [1]	4 (<1%) [1]
Urinary tract infection	2 (<1%)	4 (<1%)
Lung neoplasm malignant	2 (<1%)	2 (<1%)
Renal impairment	2 (<1%) [1]	2 (<1%) [1]
Traumatic hematoma	2 (<1%)	2 (<1%) [1]
Upper gastrointestinal hemorrhage	2 (<1%) [2]	2 (<1%) [2]
Aortic dissection	2 (<1%)	1 (<1%)
Chronic obstructive pulmonary disease	2 (<1%)	1 (<1%)
Duodenal ulcer hemorrhage	2 (<1%) [1]	1 (<1%) [1]
Rectal hemorrhage	2 (<1%) [2]	1 (<1%) [1]
Bronchitis acute	2 (<1%)	0
Chronic lymphocytic leukemia	2 (<1%)	0
Femur fracture	2 (<1%)	0
Hematemesis	2 (<1%) [2]	0
Hepatic neoplasm malignant	2 (<1%)	0
Osteoarthritis	2 (<1%)	0
Phlebitis infective	2 (<1%)	0
Postoperative renal failure	2 (<1%)	0
Injection site hemorrhage	1 (<1%) [1]	16 (<1%) [16]
Hematoma	1 (<1%)	6 (<1%) [5]
Gastric ulcer hemorrhage	1 (<1%)	5 (<1%) [5]
Hemorrhage intracranial	1 (<1%) [1]	3 (<1%) [3]
Cholecystitis	1 (<1%)	2 (<1%)
Multi-organ failure	1 (<1%)	2 (<1%) [1]
Muscle hemorrhage	1 (<1%) [1]	2 (<1%) [2]
Pancreatitis acute	1 (<1%)	2 (<1%)
Pleural effusion	1 (<1%)	2 (<1%)
Pneumothorax	1 (<1%)	2 (<1%)
Renal failure chronic	1 (<1%)	2 (<1%)
Respiratory arrest	1 (<1%) [1]	2 (<1%) [1]
Urosepsis	1 (<1%)	2 (<1%)
Abdominal pain	1 (<1%)	1 (<1%)
Air embolism	1 (<1%)	1 (<1%)
Anemia postoperative	1 (<1%)	1 (<1%) [1]
Anaphylactic shock	1 (<1%)	1 (<1%) [1]
Aortic aneurysm rupture	1 (<1%) [1]	1 (<1%)
Brain neoplasm	1 (<1%)	1 (<1%)
Cellulitis	1 (<1%)	1 (<1%)
Cholelithiasis	1 (<1%)	1 (<1%)
Colon cancer	1 (<1%)	1 (<1%)
Graft thrombosis	1 (<1%) [1]	1 (<1%)
Hemoglobin decreased	1 (<1%) [1]	1 (<1%) [1]

Infection	1 (<1%)	1 (<1%)
Iron deficiency anemia	1 (<1%)	1 (<1%)
Low cardiac output syndrome	1 (<1%)	1 (<1%)
Post procedural hematoma	1 (<1%)	1 (<1%)
Postoperative wound infection	1 (<1%)	1 (<1%)
Respiratory distress	1 (<1%)	1 (<1%)
Respiratory tract infection	1 (<1%)	1 (<1%)
Septic shock	1 (<1%)	1 (<1%)
Subarachnoid hemorrhage	1 (<1%) [1]	1 (<1%) [1]
Abdominal strangulated hernia	1 (<1%)	0
Acute respiratory distress syndrome	1 (<1%)	0
Agitation	1 (<1%)	0
Alcohol withdrawal syndrome	1 (<1%)	0
Aortic valve stenosis	1 (<1%)	0
Apallic syndrome	1 (<1%)	0
Arterial thrombosis limb	1 (<1%)	0
Artery dissection	1 (<1%)	0
Autoimmune thyroiditis	1 (<1%)	0
Bacterial infection	1 (<1%)	0
Bladder cancer	1 (<1%)	0
Blood glucose abnormal	1 (<1%)	0
Bronchopneumopathy	1 (<1%)	0
Cardiac monitoring abnormal	1 (<1%)	0
Cerebral hematoma	1 (<1%) [1]	0
Chronic leukemia	1 (<1%)	0
Clostridium colitis	1 (<1%)	0
Coma	1 (<1%)	0
Confusional state	1 (<1%)	0
Cough	1 (<1%)	0
Coxsackie pericarditis	1 (<1%)	0
Diabetes mellitus	1 (<1%)	0
Diabetic foot	1 (<1%)	0
Diagnostic procedure	1 (<1%)	0
Ear infection	1 (<1%)	0
Endocarditis	1 (<1%)	0
Epistaxis	1 (<1%)	0
Eye hemorrhage	1 (<1%) [1]	0
Femoral artery dissection	1 (<1%)	0
Gastric ulcer perforation	1 (<1%)	0
Gastroesophageal reflux disease	1 (<1%)	0
Heparin-induced thrombocytopenia	1 (<1%)	0
Hepatic cirrhosis	1 (<1%)	0
Hypokalemia	1 (<1%)	0
Hypotension	1 (<1%)	0
Intracardiac thrombus	1 (<1%)	0

Lung infection	1 (<1%)	0
Mediastinitis	1 (<1%)	0
Muscle spasms	1 (<1%)	0
Myocardial infarction	1 (<1%)	0
Nephritis interstitial	1 (<1%) [1]	0
Nephrolithiasis	1 (<1%)	0
Nervous system disorder	1 (<1%)	0
Oesophageal varices hemorrhage	1 (<1%) [1]	0
Opisthorchiasis	1 (<1%)	0
Pancytopenia	1 (<1%) [1]	0
Peritonitis	1 (<1%)	0
Plasmacytoma	1 (<1%)	0
Pneumonia bacterial	1 (<1%)	0
Procedural complication	1 (<1%) [1]	0
Prostatitis	1 (<1%)	0
Psychotic disorder	1 (<1%)	0
Rash macular	1 (<1%) [1]	0
Renal artery stenosis	1 (<1%)	0
Renal cell carcinoma stage unspecified	1 (<1%)	0
Skin ulcer	1 (<1%)	0
Staphylococcal bacteremia	1 (<1%)	0
Staphylococcal sepsis	1 (<1%)	0
Subileus	1 (<1%)	0
Thrombosis in device	1 (<1%) [1]	0
Transaminases increased	1 (<1%) [1]	0
Traumatic hemorrhage	1 (<1%) [1]	0
Tuberculosis	1 (<1%)	0
Tumor hemorrhage	1 (<1%) [1]	0
Upper respiratory tract infection	1 (<1%)	0
Urogenital hemorrhage	1 (<1%) [1]	0
Vaginal hemorrhage	1 (<1%) [1]	0
Retroperitoneal hematoma	0	10 (<1%) [8]
Operative hemorrhage	0	4 (<1%) [2]
Pyrexia	0	4 (<1%)
Acute respiratory failure	0	3 (<1%)
Hemoptysis	0	3 (<1%) [2]
Hemorrhage	0	3 (<1%) [3]
Abdominal hematoma	0	2 (<1%) [2]
Bradycardia	0	2 (<1%)
Coronary artery occlusion	0	2 (<1%) [2]
Deep vein thrombosis	0	2 (<1%)
Gastrointestinal ulcer hemorrhage	0	2 (<1%) [2]
Hematoma infection	0	2 (<1%)
Hyperthyroidism	0	2 (<1%)
Intermittent claudication	0	2 (<1%)
Melena	0	2 (<1%) [1]

Peripheral ischemia	0	2 (<1%)
Pleural hemorrhage	0	2 (<1%) [2]
Venous thrombosis	0	2 (<1%)
Anaphylactic reaction	0	1 (<1%)
Apnea	0	1 (<1%)
Appendicitis	0	1 (<1%)
Arteriovenous fistula	0	1 (<1%)
Bacteraemia	0	1 (<1%)
Bladder cancer recurrent	0	1 (<1%)
Bronchitis	0	1 (<1%)
Bronchopneumonia	0	1 (<1%)
Burkitt's lymphoma	0	1 (<1%)
Cerebral hemorrhage	0	1 (<1%) [1]
Chondrocalcinosis pyrophosphate	0	1 (<1%)
Colitis	0	1 (<1%)
Colonic polyp	0	1 (<1%)
Contusion	0	1 (<1%)
Cystitis hemorrhagic	0	1 (<1%)
Dementia	0	1 (<1%)
Diabetes mellitus insulin-dependent	0	1 (<1%)
Diabetic coma	0	1 (<1%)
Diabetic gangrene	0	1 (<1%)
Diplopia	0	1 (<1%)
Dressler's syndrome	0	1 (<1%)
Drug hypersensitivity	0	1 (<1%)
Dyspepsia	0	1 (<1%)
Embolism	0	1 (<1%)
Femoral artery aneurysm	0	1 (<1%)
Gastritis	0	1 (<1%)
Gastrointestinal disorder	0	1 (<1%)
Groin pain	0	1 (<1%)
Hemorrhage subcutaneous	0	1 (<1%) [1]
Hemorrhoidal hemorrhage	0	1 (<1%)
Hepatic enzyme increased	0	1 (<1%)
Hepatic failure	0	1 (<1%)
Hepatic mass	0	1 (<1%)
Hip fracture	0	1 (<1%)
Hodgkin's disease	0	1 (<1%)
Hyperkalaemia	0	1 (<1%)
Hypersensitivity	0	1 (<1%) [1]
Hypertriglyceridemia	0	1 (<1%)
Hyponatremia	0	1 (<1%)
Hypovolemic shock	0	1 (<1%)
Inguinal hernia, obstructive	0	1 (<1%)
Injection site abscess	0	1 (<1%)

Injection site infection	0	1 (<1%)
Interstitial lung disease	0	1 (<1%)
Intervertebral disc degeneration	0	1 (<1%)
Intestinal mass	0	1 (<1%)
Intestinal obstruction	0	1 (<1%)
Lower respiratory tract infection	0	1 (<1%)
Lung adenocarcinoma	0	1 (<1%)
Mediastinal mass	0	1 (<1%)
Mesenteric artery embolism	0	1 (<1%)
Mesenteric artery stenosis	0	1 (<1%)
Metastases to liver	0	1 (<1%)
Mitral valve disease	0	1 (<1%)
Muscular weakness	0	1 (<1%) [1]
Musculoskeletal pain	0	1 (<1%) [1]
Myasthenia gravis crisis	0	1 (<1%)
Oesophageal hemorrhage	0	1 (<1%)
Papillary muscle rupture	0	1 (<1%)
Peptic ulcer	0	1 (<1%)
Peptic ulcer hemorrhage	0	1 (<1%) [1]
Phlebitis	0	1 (<1%)
Pleural mesothelioma malignant	0	1 (<1%)
Pneumonia aspiration	0	1 (<1%)
Pneumonitis	0	1 (<1%)
Postoperative infection	0	1 (<1%)
Prostate cancer	0	1 (<1%)
Psoas abscess	0	1 (<1%)
Pulmonary alveolar hemorrhage	0	1 (<1%) [1]
Pulmonary fibrosis	0	1 (<1%)
Pulmonary mass	0	1 (<1%)
Renal colic	0	1 (<1%)
Shock hemorrhagic	0	1 (<1%) [1]
Squamous cell carcinoma	0	1 (<1%)
Subdural hematoma	0	1 (<1%)
Thrombophlebitis	0	1 (<1%)
Thrombophlebitis septic	0	1 (<1%)
Tooth abscess	0	1 (<1%)
Toxic nodular goitre	0	1 (<1%)
Urethral hemorrhage	0	1 (<1%)
Urinary retention	0	1 (<1%)
Urticaria	0	1 (<1%) [1]
Vomiting	0	1 (<1%)
Wrist fracture	0	1 (<1%)

Conclusion: See publication below.

Publications:

MICHELANGELO OASIS 5 Steering Committee. Design and rationale of the MICHELANGELO Organization to Assess Strategies in Acute Ischemic Syndromes (OASIS)-5 trial program evaluating fondaparinux, a synthetic factor Xa inhibitor, in patients with non-ST-segment elevation acute coronary syndromes. *Am Heart J.* 2005;150:1107.e1-e10

Yusuf S, Mehta SR et al Comparison of Fondaparinux and Enoxaparin in Acute Coronary Syndromes.. *N Engl J Med.* 2006;354:1464-1476.

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