

Clinical trials of Enoxaparin

TrialResults-center www.trialresultscenter.org

1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
Enoxaparin vs placebo			
AMI-SK , 2002 n=253/243 follow-up: 30 d	Enoxaparin 30 mg IV bolus, 1 mg/kg for 38 d versus placebo	patients with evolving myocardial infarction, Age >=18 y, STEMI	Parallel groups Double-blind
Enoxaparin vs UFH			
ASSENT 3 Plus , 2003 n=818/821 follow-up: 30 d	Enoxaparin 1 mg/kg BID, <=7d versus UFH 60 IU/kg, then 12 IU/kg per h for >=3d	patients with ST-elevation myocardial infarction	Parallel groups open
ASSENT 3 , 2001 n=2040/2038 follow-up: 65279;30 d	65279;Enoxaparin 1 mg/kg BID, <=7d versus UFH 65279;60 U/kg bolus, then 12 IU/kg per h for 48 h	patients with acute myocardial infarction	Parallel groups open
Baird , 2002 n=149/151 follow-up: 90 d	Enoxaparin 40 mg TID, 4 d versus UFH 5000 IU bolus, then 30 000 IU over 24 h for 4d	patients receiving fibrinolytic therapy following acute myocardial infarction	Parallel groups 90-min TIMI flow
ENTIRE-TIMI 2 , 2002 n=160/82 follow-up: 30 d	Enoxaparin 1 mg/kg BID, <=8d versus UFH 60 IU/kg, then 12 IU/kg per h for >=3d	Patients with ST-elevation MI presenting <6 hours from symptom onset were	Parallel groups open
HART II , 2001 n=200/200 follow-up: 57 d	Enoxaparin 1 mg/kg BID, <=3d versus UFH 40005000 IU bolus, then 15 IU/kg per hour for >=3d	patients undergoing reperfusion therapy with an accelerated recombinant tissue plasminogen activator regimen and aspirin for AMI	Parallel groups open

More details and results :

- antithrombotics for acute myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q36>
- heparin (UFH or LMWH) for acute myocardial infarction in patients eligible to receive fibrinolytic therapy at <http://www.trialresultscenter.org/go-Q308>

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ASSENT 3 Plus, 2003:

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ENTIRE-TIMI 2, 2002:

Antman EM, Louwerenburg HW, Baars HF, Wesdorp JC, Hamer B, Bassand JP, Bigonzi F, Pisapia G, Gibson CM, Heidbuchel H, Braunwald E, Van de Werf F Enoxaparin as adjunctive antithrombin therapy for ST-elevation myocardial infarction: results of the ENTIRE-Thrombolysis in Myocardial Infarction (TIMI) 23 Trial. Circulation 2002;105:1642-9 [11940541]

HART II, 2001:

Ross AM, Molhoek P, Lundergan C, Knudtson M, Draoui Y, Regalado L, Le Louer V, Bigonzi F, Schwartz W, de Jong E, Coyne K Randomized comparison of enoxaparin, a low-molecular-weight heparin, with unfractionated heparin adjunctive to recombinant tissue plasminogen activator thrombolysis and aspirin: second trial of Heparin and Aspirin Reperfusion Therapy (HART II). Circulation 2001;104:648-52 [11489769]

2 heart failure

Trial	Treatments	Patients	Trials design and methods
enoxaparin vs UFH			
THE-PRINCE (Kleber) , 2003 n=164/169 follow-up:	enoxaparin 40mg once daily for 10+/-2 days versus UFH 5000 IU 3 times daily for 10+/-2 days	patients hospitalized for severe respiratory disease or heart failure (NYHA III, IV)	Parallel groups open germany

More details and results :

- antithrombotics for heart failure in patients hospitalized for heart failure at <http://www.trialresultscenter.org/go-Q72>

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THE-PRINCE (Kleber), 2003:

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3 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
enoxaparin vs unfractionated heparin			
RESCUE [NCT00077818] n=NA follow-up: 30 days	Enoxaparin versus unfractionated heparin	patients diagnosed with acute coronary syndrome in the emergency department	Parallel groups open
enoxaparin vs tinzaparin			
EVET , 2005 n=220/218 follow-up: 30 days	enoxaparin, 100 IU/kg subcutaneously twice daily +aspirin for 7 days versus tinzaparin, 175 IU/kg subcutaneously once daily +aspirin for 7 days	patients with non-ST-segment elevation acute coronary syndromes	Parallel groups open
enoxaparin vs UFH (on top of aspirin)			
ESSENCE , 1997 n=1607/1564 follow-up: 14 days (30 days)	enoxaparin 1mg/kg, twice daily during 48h-8days versus continuous intravenous unfractionated heparin	patients with angina at rest or nonQ-wave myocardial infarction	Parallel groups Double blind United states, Canada, South America, Europe
INTERACT , 2006 n=380/366 follow-up: 30 days (2.5y)	enoxaparin (1 mg/kg subcutaneously twice daily) for 48 hours (+eptifibatide and aspirin) versus intravenous UFH (70 U/kg bolus followed by 15 U/kg per hour adjusted to an activated partial thromboplastin time of 1.5-2 times control) for 48 hours (+eptifibatide and aspirin)	high-risk patients with ACS receiving aspirin and eptifibatide	Parallel groups open Canada
SYNERGY , 2005 [NCT00043784] n=4993/4985 follow-up: 30 days	Enoxaparin 1 mg/kg twice daily versus unfractionated heparin	high-risk patients with acute coronary syndromes	Parallel groups open 12 countries

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Trial	Treatments	Patients	Trials design and methods
TIMI 11 B (long term) , 1998 n=1953/1957 follow-up: 43 days	enoxaprin during both the acute phase (IV) and outpatient phase (SC) versus intravenous UFH for >=3 days (followed by subcutaneous placebo injections)	unstable angina/nonQ-wave myocardial infarction	double blind North America, South America,
TIMI 11 B (short term) , 1998 n=1953/1957 follow-up: 8 days (43 days)	enoxaprin during both the acute phase and outpatient phase versus intravenous UFH for >=3 days (followed by subcutaneous placebo injections)	unstable angina/nonQ-wave myocardial infarction	Parallel groups double blind North America, South America,

More details and results :

- antithrombotics for acute coronary syndrome in all type of patients at <http://www.trialresultscenter.org/go-Q24>
- antithrombotics for acute coronary syndrome in unstable angina at <http://www.trialresultscenter.org/go-Q35>
- heparin (UFH or LMWH) for acute coronary syndrome in all type of patients at <http://www.trialresultscenter.org/go-Q171>

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EVET, 2005:

Katsouras C, Michalis LK, Papamichael N, Adamides K, Naka KK, Nikas D, Goudevenos JA, Sideris DA Enoxaparin versus tinzaparin in non-ST-segment elevation acute coronary syndromes: results of the enoxaparin versus tinzaparin (EVET) trial at 6 months. *Am Heart J* 2005;150:385-91 [[16169312](#)]

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TIMI 11 B (short term), 1998:

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4 DVT prophylaxis

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Trial	Treatments	Patients	Trials design and methods
enoxaparin vs control			
Canata , 2003 n=18/18 follow-up: 6 days	enoxaparin sc daily (dose not specified) versus no treatment	ACL reconstruction for symptomatic ACL-deficient knees	Parallel groups Italy
enoxaparin vs no treatment			
Ho [43] n=134/169	Enoxaparin 4000 anti-Xa units versus No treatment	-	Open
Warwick , 1995 n=78/78 follow-up: 8-10 days	enoxaparin 4000x1 + elastic stockings versus no treatment + elastic stockings	Elective hip	open
enoxaparin vs placebo			
LIFENOX , 2011 [NCT00622648] n=4171/4136 follow-up: 30 days	subcutaneous enoxaparin 40 mg daily for 104 days versus placebo	hospitalized, acutely ill medical patients	Parallel groups double-blind China, India, Korea, Malaysia, Mexico, the Philippines, and Tunisia

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Trial	Treatments	Patients	Trials design and methods
Lederle , 2006 n=140/140 follow-up: 90 days	Enoxaparin 40 mg once daily, until hospital discharge versus placebo	Hospitalization in general medical unit	Parallel groups double blind
Samama , 1999 n=291/288 follow-up: 6-14 days	Enoxaparin 20 mg or 40 mg once daily, 614 days versus placebo	Acute decompensated chronic obstructive pulmonary disease with mechanical ventilation	Parallel groups double blind
Kalodiki , 1996 n=13/14 follow-up: discharge (8-12 days)	enoxaparin 4000x1 versus Placebo	Elective hip	double blind
LeGagneux , 1987 n=44/45	Enoxaparin 6000 anti-Xa units versus 65279;Placebo	prostatectomy surgery	65279;Blind
Leclerc , 1991 n=65/64 follow-up: 14 days	Enoxaparin 3000 x2 versus Placebo	Knee	double blind
Samama , 1997 n=85/85 follow-up: 8-12 days	enoxaparin 4000x1+elastic stockings versus Placebo+elastic stockings	Elective hip	double blind
Turpie , 1986 n=50/50 follow-up: 14 days or discharge	Enoxaparin 3000 x2 versus Placebo	Elective hip	double blind
Agnelli , 1998 n=153/154 follow-up: 30 days	Enoxaparin, 40 mg/d subcutaneously within 24 hours postoperatively plus compression stockings for >=7 days versus compression stockings + placebo	Elective neurosurgery, 18 years or older, without excess bleeding risk	
Melon , 1987 n=67/63 follow-up: NA	Enoxaparin, 20 mg/d subcutaneously 18-24 hours postoperatively for 10 days versus placebo	Neurosurgery, adult, 45-90 kg of weight, without excess bleeding risk	
enoxaparin vs Dextran			
DES Group , 1991 n=120/126	Enoxaparin versus Dextran	Elective hip	
out of hospital Enoxaparin vs standard prophylaxis			

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Trial	Treatments	Patients	Trials design and methods
Bergqvist , 1996 n=117/116	65279;in hospital thromboprophylaxis followed by out of hospital Enoxaparin 40 mg once a day for a total duration of 30 days versus 65279;Enoxaparin 40 mg once a day for 10-11 days	65279;THR	
Planes , 1996 n=90/89	65279;in hospital thromboprophylaxis followed by out of hospital Enoxaparin 40 mg once a day for a total duration of 35 days versus Enoxaparin 40 mg once a day for 13-15 days	THR	
Comp , 2001 n=441/432	65279;in hospital thromboprophylaxis followed by out of hospital Enoxaparin 40 mg once a day for a total duration of 27-29 days versus Enoxaparin 30 mg twice a day for 7-10 days	THR or TKR	
enoxaparin vs UFH			
Bergmann and Neuhart , 1996 n=NA follow-up: 10 days	enoxaparin 20 mg once daily for 10 days versus unfractionated heparin (UFH) 5000 IU twice daily	elderly in-patients bedridden for an acute medical illness	Parallel groups double-blind
Lechler , 1996 n=NA follow-up: 7 days	enoxaparin 40 mg versus unfractionated heparin (Ca-heparin), 3 x 5,000 U)	hospitalized medical patients	Parallel groups double-blind
Kleber , 2003 n=NA follow-up: 10 +/- 2 days	enoxaparin 40 mg once daily for 10 +/-2 days versus UFH 5000 IU 3 times daily for 10 +/-2 days	severe respiratory disease or heart failure	Parallel groups open Germany
enoxaparin vs Unfractionated heparin			
Samama 2 , 1988 n=127/123 follow-up: 7 days	Enoxaparin 4000 versus UFH 15 000 units	General surgery	Open

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Trial	Treatments	Patients	Trials design and methods
Samama 1 , 1988 n=168/167 follow-up: 7 days	Enoxaparin 2000 versus UFH 15 000 units	General surgery	Open
Levine , 1991 n=333/332	Enoxaparin versus Unfractionated heparin	Elective hip	
Samama 3 , 1988 n=160/147 follow-up: 7 days	Enoxaparin 6000 versus UFH 15 000 units	General surgery	Open
Planes , 1988 n=124/113	Enoxaparin versus Unfractionated heparin	Elective hip	
Kaaja , 1992 n=37/31	Enoxaparin 2000 anti Xa units versus UFH 10 000 units	Gynaecological surgery	Blind
Gazzaniga (ISG) , 1993 n=561/561	Enoxaparin 2000 anti Xa units versus UFH 10 000 units	General and vascular surgery	Open
Nurmohamed , 1995 n=737/734	Enoxaparin 2000 anti Xa units versus UFH 15 000 units	General surgery	Blind
McLeod (Canadian) , 1995 n=674/675	Enoxaparin 4000 anti Xa units versus UFH 15 000 units	Colorectal surgery	Blind
Gonzalez , 1996 n=84/82	Bemiparin 2500 anti Xa units versus UFH 10 000 units	Abdominal surgery	Blind
ENOXACAN , 1997 n=555/560	Enoxaparin 4000 anti Xa units versus UFH 15 000 units	Abdominopelvic surgery	Blind

More details and results :

- antithrombotics for DVT prophylaxis in orthopedic surgery at <http://www.trialresultscenter.org/go-Q37>
- antithrombotics for DVT prophylaxis in elective major knee surgery at <http://www.trialresultscenter.org/go-Q38>
- antithrombotics for DVT prophylaxis in elective hip replacement at <http://www.trialresultscenter.org/go-Q39>
- antithrombotics for DVT prophylaxis in medical patients at <http://www.trialresultscenter.org/go-Q87>

- antithrombotics for DVT prophylaxis in general surgery at <http://www.trialresultscenter.org/go-Q92>
- antithrombotics for DVT prophylaxis in urologic surgery at <http://www.trialresultscenter.org/go-Q93>
- antithrombotics for DVT prophylaxis in gynaecological surgery at <http://www.trialresultscenter.org/go-Q94>
- antithrombotics for DVT prophylaxis in abdominal surgery at <http://www.trialresultscenter.org/go-Q96>
- antithrombotics for DVT prophylaxis in neurosurgery at <http://www.trialresultscenter.org/go-Q99>
- antithrombotics for DVT prophylaxis in arthroscopy at <http://www.trialresultscenter.org/go-Q150>
- heparin (UFH or LMWH) for DVT prophylaxis in orthopedic surgery at <http://www.trialresultscenter.org/go-Q189>
- LMWH for DVT prophylaxis in orthopedic surgery at <http://www.trialresultscenter.org/go-Q190>
- UFH for DVT prophylaxis in urologic surgery at <http://www.trialresultscenter.org/go-Q194>
- heparin (UFH or LMWH) for DVT prophylaxis in general surgery at <http://www.trialresultscenter.org/go-Q195>
- LMWH for DVT prophylaxis in general surgery at <http://www.trialresultscenter.org/go-Q196>
- heparin (UFH or LMWH) for DVT prophylaxis in neurosurgery at <http://www.trialresultscenter.org/go-Q197>
- LMWH for DVT prophylaxis in neurosurgery at <http://www.trialresultscenter.org/go-Q198>
- LMWH for DVT prophylaxis in gynaecological surgery at <http://www.trialresultscenter.org/go-Q200>
- LMWH for DVT prophylaxis in abdominal surgery at <http://www.trialresultscenter.org/go-Q202>

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Nurmohamed, 1995:

McLeod (Canadian), 1995:

Gonzalez, 1996:

ENOXACAN, 1997:

5 venous thrombosis

Trial	Treatments	Patients	Trials design and methods
Enoxaparin vs acenocoumarol			
Veiga , 2000 n=50/50 follow-up: 6-9 mo	UFH, APTT 1.52.0d followed by Enoxaparin 4,000 IU qd versus UFH, APTT 1.52.0d followed by Acenocoumarol target INR 2-3	patients with objective diagnosis of DVT by Venography	open
Enoxaparin vs coumarin			
Gonzlez-Fajardo , 2008 n=85/80 follow-up: 1y, 5y	long-term anticoagulant treatment with enoxaparin during at least 3 months versus long-term anticoagulant treatment with coumarin during at least 3 months	patients with symptomatic, unilateral, first-episode DVT	Parallel groups open, blind assessment Spain
extended enoxaparin vs standard treatment			
Cesarone , 2003 n=NA follow-up: 3 months	Enoxaparin 100UL/Kg twice daily for 3 months versus coumadin (target INR 3) for 3 months.	patients with cancer with DVT	Parallel groups NA
Deitcher , 2006 n=NA follow-up: 12 months	Enoxaparin 1mg/kg twice daily for 5 days followed by 1-1.5mg/kg daily for 175 days versus Enoxaparin 1mg/kg twice daily for 5 days followed by warfarin (target INR 2-3) for a total of 180 days	patients with cancer with DVT and/or PE	Parallel groups none
Meyer , 2002 n=NA follow-up: 3 months	Enoxaparin 1.5 mg/kg daily for 3 monthsmag versus Enoxaparin 1.5 mg/kg daily for 4 days followed by warfarin (target INR 2-3) for 3 months	patients with cancer (solid or hematological; active or in remission but on treatment); with pulmonary embolism and/or DVT and a minimum life expectancy of 3 months	Parallel groups outcome assessment blinded

continued...

Trial	Treatments	Patients	Trials design and methods
Enoxaparin vs warfarin			
Deitcher , 2003 n=51/30 follow-up: 6 mo	LMWH: 1a, 1 mg/kg q12h; 1b, 1 mg/kg qd12h followed by Enoxaparin 1a: 1 mg/kg qd; 1b: 1.5 mg/kg qd versus LMWH, 1 mg/kg q12h followed by Warfarin target INR 2-3	patients with objective diagnosis of DVT	open
Meyer , 2002 n=71/58 follow-up: 3 mo	LMWH, 1.5 mg/kg qd followed by Enoxaparin 1.5 mg/Kg qd versus LMWH, 1.5 mg/kg qd followed by Warfarin target INR 2-3	patients with cancer and objective diagnosis of DVT by Venography/compression ultrasonography	open
Gonzalez-Fajardo , 1999 n=93/92 follow-up: 9 mo	LMWH, 4,000 IU bid followed by Enoxaparin 4,000 IU qd versus UFH followed by Warfarin target INR 2-3	patients with objective diagnosis of DVT by Venography	Parallel groups open
Pini , 1994 n=93/94 follow-up: 9 mo	UFH, APTT 1.31.9 followed by Enoxaparin 4,000 IU qd versus UFH, APTT 1.31.9 followed by Warfarin target INR 2-3.5	patients with objective diagnosis of DVT by Venography (diagnosed by strain-gauge plethysmography plus D-dimer latex assay and confirmed by venography)	open
once daily enoxaparin vs twice daily enoxaparin			
Merli , 2001 n=298/312 follow-up:	enoxaparin 1.5 mg/kg body weight once daily versus S.c. enoxaparin at fixed dosages of 1.0 mg/kg of body weight twice daily	patients with a symptomatic lower-extremity DVT confirmed by venography or ultrasonography (including patients with confirmed PE)	Parallel groups double blind Europe, United States of America and Australia, image/pj
once daily enoxaparin vs UFH			
Merli (once daily vs UFH) , 2001 n=298/290 follow-up: 3 months	Initial therapy with enoxaparin 1.5 mg/kg body weight once daily versus Initial therapy with dose-adjusted intravenous unfractionated heparin	patients with a symptomatic lower-extremity DVT confirmed by venography or ultrasonography (including patients with confirmed PE)	Parallel groups partialy blinded Europe, United States of America and Australia, image/pj
Enoxaparin vs unfractionated heparin			
Simonneau et al , 1993 n=67/67 follow-up: 3 Months	Enoxaparin Subcutaneous twice daily for 0 Days, 100 U/kg BID versus unfractionated heparin intravenous APPTx1.5-2.5	-	

More details and results :

- antithrombotics for venous thrombosis in all type of patients at <http://www.trialresultscenter.org/go-Q101>
- antithrombotics for venous thrombosis in patients with cancer at <http://www.trialresultscenter.org/go-Q103>
- LMWH for venous thrombosis in all type of patients at <http://www.trialresultscenter.org/go-Q203>
- heparin (UFH or LMWH) for venous thrombosis in all type of patients at <http://www.trialresultscenter.org/go-Q204>

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6 percutaneous coronary intervention

Trial	Treatments	Patients	Trials design and methods
enoxaparin vs UFH			
ATOLL , 2010 n=450/460 follow-up: 30 days	IV enoxaparin versus UFH	patients undergoing PCI for acute STEMI	Parallel groups open Austria, France, Germany, and US
Brieger n=346/234 follow-up:	enoxaparin versus unfractionated heparin	patients undergoing percutaneous coronary intervention for ST-segment elevation myocardial infarction (STEMI)	
CRUISE , 2003 n=129/132 follow-up: 2,7 +30 days	Enoxaparin 0.75 mg/kg bolus versus 65279;UFH 60 IU/kg bolus, then titrated to ACT >200	Urgent or elective PCI	Parallel groups open
Drozd , 2001 n=50/50 follow-up: 24hrs, 30 days	65279;Enoxaparin 1 mg/kg bolus versus UFH 100 IU/kg bolus	PCI for stable angina	
Dudek , 2000 n=200/200 follow-up: 3 days	Enoxaparin 1 mg/kg bolus versus UFH titrated to ACT >300	PCI	

continued...

Trial	Treatments	Patients	Trials design and methods
Dudek b (enox alone) , 2000 n=NA follow-up:	Enoxaparin 1 mg/kg bolus versus UFH titrated to ACT >300	PTCA complex lesionsCI	
Galeote , 2001 n=50/49 follow-up:	Enoxaparin 0.75 mg/kg bolus versus UFH 70 U/kg bolus, then titrated to ACT >200	PTCA patients with stable/unstable angina or AMI	
Rabah , 1999 n=30/30 follow-up:	Enoxaparin 1 mg/kg bolus versus 65279;UFH 10,000 IU bolus, then titrated to ACT >300	PCI for stable angina	Parallel groups open
STEEPLE , 2006 [NCT00077844] n=NA follow-up:	enoxaparin (0.5 or 0.75 mg per kilogram of body weight) versus unfractionated heparin (adjusted for activated clotting time)	elective percutaneous coronary intervention.	Parallel groups open
enoxaparin+abciximab vs UFH			
Dubek b (+abciximal) , 2001 n=NA	Enoxaparin 0.75 mg/kg bolus + abciximab versus UFH titrated to ACT >300	-	
enoxaparin vs unfractionated heparin			
STREAM <i>ongoing</i> [NCT00882635] n=NA follow-up:	Enoxaparin versus Unfractionated Heparin	St Elevation Myocardial Infarction patients undergoing primary percutaneous coronary intervention	

More details and results :

- antithrombotics for percutaneous coronary intervention in all type of patients at <http://www.trialresultscenter.org/go-Q63>
- antithrombotics for percutaneous coronary intervention in MI patients undergoing primary PCI at <http://www.trialresultscenter.org/go-Q291>
- anticoagulant for percutaneous coronary intervention in all type of patients at <http://www.trialresultscenter.org/go-Q388>
- anticoagulant for percutaneous coronary intervention in patients undergoing primary PCI at <http://www.trialresultscenter.org/go-Q457>

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7 pulmonary embolism

Trial	Treatments	Patients	Trials design and methods
Enoxaparin vs unfractionated heparin			
PREPIC , 1998 n=41/54 follow-up: 2 y	Enoxaparin, 1 mg/kg twice daily, 8-12 days versus Unfractionated heparin: bolus 5000 IU, infusion 500 IU/kg per day	patients with proximal deep-vein thrombosis who were at risk for pulmonary embolism	Factorial plan open
Merli sub group , 2001 n=199/88 follow-up: 3 mo	Enoxaparin, 1mg/kg twice daily or 1.5 mg/kg once daily, 5 days versus Unfractionated heparin: according nomogram at local institution	patients with confirmed pulmonary embolism	Parallel groups open 16 countries

More details and results :

- antithrombotics for pulmonary embolism in all type of patients at <http://www.trialresultscenter.org/go-Q102>

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8 superficial thrombophlebitis

Trial	Treatments	Patients	Trials design and methods
enoxaparin vs placebo			
STENOX (enoxaparin 1.5mg/hg) , 2003 n=NA follow-up:	enoxaparin (s.c. 1.5 mg/kg)for 8-12 days versus placebo	patients with St of at least 5 cm on ultrasonography examination	

continued...

Trial	Treatments	Patients	Trials design and methods
Stenox (enoxaparin 40mg) , 2003 n=NA follow-up:	LMWH (enoxaparin) (s.c. 40 mg) for 8-12 days versus placebo.	patients with ST of at least 5 cm on ultrasonography examination	

More details and results :

- antithrombotics for superficial thrombophlebitis in superficial thrombophlebitis of the leg at <http://www.trialresultscenter.org/go-Q218>

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Entry terms: enoxaparin, Lovenox, Clexane