Clinical trials of nadroparin

TrialResults-center www.trialresultscenter.org

1 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
nadroparin vs UFH (on top of aspirin)			
FRAXIS (14 days) , 1998 n=1151/1151 follow-up: 14 days	nadroparin for 14 days versus unfractionated heparin for 14 days	unstable angina or non-Q wave myocardial infraction	double blind 17 countries
FRAXIS (6days) , 1998 n=1166/1151 follow-up: 14 days	nadroparin for 6 days (+aspirin) versus unfractionated heparin for 6 days (+aspirin)	unstable angina or non-Q wave myocardial infraction	Parallel groups Double blind 17 countries

More details and results :

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

References

FRAXIS (14 days), 1998:

Comparison of two treatment durations (6 days and 14 days) of a low molecular weight heparin with a 6-day treatment of unfractionated heparin in the initial management of unstable angina or non-Q wave myocardial infarction: FRAX.I.S. (FRAxiparine in Ischaemic Syndrome). Eur Heart J 1999;20:1553-62 [10529323]

FRAXIS (6days), 1998:

Comparison of two treatment durations (6 days and 14 days) of a low molecular weight heparin with a 6-day treatment of unfractionated heparin in the initial management of unstable angina or non-Q wave myocardial infarction: FRAX.I.S. (FRAxiparine in Ischaemic Syndrome). Eur Heart J 1999;20:1553-62 [10529323]

2 DVT prophylaxis

Trial	Treatments	Patients	Trials design and methods
nadroparin vs control			

continued...

Trial	Treatments	Patients	Trials design and methods
KANT (7 days) , 2008 n=657/660 follow-up: 3 months	once-daily subcutaneous injection of LMWH (nadroparin, 3800 anti-Xa IU) for 7 days versus full-length graduated compression stocking for 7 days	patients undergoing knee arthroscopy	Parallel groups open (blinded assessment) Italy
Roth , 1995 n=61/61 follow-up: 4 days	0.3 ml sc fraxiparine 2 hours before the operation and self administered daily (except the firstvtwo doses) for 4 days after surgeryn/x versus no treatment	patients undergoing ambulatory arthroscopic	Parallel groups Germany
Kujath , 1993 n=126/126 follow-up: 65279;16 days	Nadroparin 2850 IU versus no prophylaxis	patients with injuries of the lower limb immobilized by a plaster cast	Parallel groups open
nadroparin 14d vs control			
KANT (14 days) , 2008 n=444/660 follow-up: 3 months	once-daily subcutaneous injection of LMWH (nadroparin, 3800 anti-Xa IU) for 14 days versus full-length graduated compression stocking for 7 days	patients undergoing knee arthroscopy	Parallel groups open (blinded assessment) Italy
nadroparin vs enoxaparin			
FX140, Simonneau G , 2006 n=NA follow-up:	-	-	
nadroparin vs no treatment			
Marassi [41] n=31/33	Nadroparin 2850 anti-Xa units versus No treatment	-	Open
Yoo , 1997 n=50/50 follow-up: 10 days	nadroparin 41/kgx1 days 1-3, 62/kg x1 days 4-11+elastic stockings versus no treatment	Elective hip	open
PROTECT (nadroparin) *ongoing* [NCT00881088] n=NA follow-up: 6 weeks	nadroparin 0,3 cc daily during immobilization versus no treatment	patients with a nonsurgical fracture of the lower extremity requiring immobilisation in a below-knee plaster cast	Parallel groups single blind

continued...

Trial	Treatments	Patients	Trials design and methods
nadroparin vs placebo			
Bergmann , 1996 n=NA follow-up: up to 21	nadroparin 7500 u anti-Xa once daily versus placebo	hospitalized medical	Parallel groups
Balas [40] n=94/95	Nadroparin 2850 anti-Xa units versus Placebo	-	Blind
Fraisse , 2000 n=109/114 follow-up: <=21 days	Nadroparin 38005700E once daily, Until no longer mechanical ventilation, <=21 days versus placebo	Acute decompensated chronic obstructive pulmonary diseasewith mechanical ventilation	Parallel groups double blind
Mahe , 2005 n=1230/1244 follow-up: <=21 days	nadroparin 7500E once daily, Until hospital discharge, <=21 days versus placebo	Congestive heart failure (NYHA IIIIV), acute or respiratory disease, nonpulmonary sepsis, cancer	Parallel groups double blind
Sourmelis , 1995 n=72/78 follow-up: 10-12 days	nadroparin 3075x1 preop, 6150x1 post op versus Placebo	Hip fracture	double blind
Pezzuoli , 1989 n=2247/2251 follow-up:	Nadroparin 2850 anti-Xa units versus Placebo	general surgery	Blind
Nurmohamed , 1996 n=241/244 follow-up: 56 days	Nadroparin, 7500 Institute Choay anti-Xa units per day subcutaneously 18-24 hours postoperatively plus compression for 10 days versus compression stockings + placebo	Craniotomy or spinal surgery for tumor or injury, 18 years or older, without excess bleeding risk	
out of hospital Nadroparin vs standard prophylaxis			
NPHDO , 1998 n=173/173	65279;in hospital thromboprophylaxis followed by out of hospital Nadroparin weight-adjusted for a total duration of 37-38 days versus Nadroparin weight-adjusted for 16-17 days	THR	
nadroparin vs Unfractionated heparin			
Kakkar and Murray , 1985 n=200/200 follow-up: 10 days	Nadroparin 2850 versus UFH 10 000 units	General surgery	Blind

continued...

Trial	Treatments	Patients	Trials design and methods
EFS , 1988 n=968/941 follow-up: 1 month	Nadroparin 2850 versus UFH 15 000 units	Abdominal surgery	Open
Leyvraz , 1991 n=203/206 follow-up:	Fraxiparin versus Unfractionated heparin	Elective hip	
Dahan , 1989 n=46/41 follow-up:	Nadroparin 2850 versus UFH 15 000 units	Thoracic surgery	Open
Barbui , 1990 n=171/173	Nadroparin 2850 anti Xa units versus UFH 10 000 units	General surgery	Open
Eurin , 1994 n=241/239	Nadroparin 2850 anti Xa units versus UFH 15 000 units	Abdominopelvic surgery	Open

More details and results :

- antithrombotics for DVT prophylaxis in orthopedic surgery at http://www.trialresultscenter.org/go-Q37
- antithrombotics for DVT prophylaxis in elective hip replacement at http://www.trialresultscenter.org/go-Q39
- antithrombotics for DVT prophylaxis in hip Fracture at http://www.trialresultscenter.org/go-Q40
- 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 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
- 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 abdominal surgery at http://www.trialresultscenter.org/go-Q202
- antithrombotics for DVT prophylaxis in patients with immobilization of the lower extremities at http://www.trialresultscenter.org/go-Q405

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3 venous thrombosis

Trial	Treatments	Patients	Trials design and methods
Nadroparin vs acenocoumarol			
Lopez-Beret , 2001 n=81/77 follow-up: 6-9 mo	LMWH, 1,025 IU/10 kg bid followed by Nadroparin 1,025 IU/10 kg bid versus LMWH, 1,025 IU/10 kg bid followed by Acenocoumarol target INR 2-3	patients with objective diagnosis of DVT by compression ultrasonography	open
Lopaciuk , 1999 n=101/101 follow-up: 9 mo	LMWH, 85 UI/kg bid followed by Nadroparin 85 IU/kg qd versus LMWH, 85 UI/kg bid followed by Acenocoumarol target INR 2-3	patients with objective diagnosis of DVT by Venography	open
extended nadroparin vs standard treatment			
Lopez Beret , 2001 n=NA follow-up: 12 months	Nadroparin 1.025 antiXa IU/10Kg twice daily after aadroparin 1.025AXa IU/10Kg twice daily for 3 days. After 3 months, nadroparin was switched to once daily versus acenocoumarol (target INR 2-3) for 3-6 months after nadroparin 1.025AXa IU/10Kg twice daily for 3 days	patients with known malignancy treated for symptomatic DVT of the lower limb	Parallel groups outcome assessment blinded
once daily nadroparin vs twice daily nadroparin			
Charbonnier , 1998 n=316/335 follow-up:	Once daily nadroparin 20,500 (AXa IU/ml)continued for at least 5 days versus twice daily nadroparin 10,250 (AXa IU/ml)continued for at least 5 days	patients with acute symptomatic proximal DVT in popliteal vein or above documented by venography	Parallel groups double blind Europe

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Trial	Treatments	Patients	Trials design and methods
Nadroparin vs unfractionated heparin			
Collaborative European Multicentre , 1991 n=70/66 follow-up: 12 Weeks	Nadroparin Subcutaneous twice daily for 10 Days, 90 U/kg BID versus unfractionated heparin intravenous APPTx1.5-2	-	
Prandoni et al , 1992 n=85/85 follow-up: 6 Months	Nadroparin Subcutaneous twice daily for >=0 Days, 90 U/kg BID versus unfractionated heparin intravenous APPTx1.5-2	-	
Lopaciuk et al , 1992 n=74/75 follow-up: 3 Months	Nadroparin Subcutaneous twice daily for 10 Days, 92 U/kg BID versus unfractionated heparin subcutaneous twice daily 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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4 pulmonary embolism

Trial	Treatments	Patients	Trials design and methods
Nadroparin vs unfractionated heparin			
European multicentre study , 1991 n=61/47 follow-up: 3 mo	Nadroparin, 47506650 antifactor Xa IU twice daily, 10 days versus Unfractioned heparin: no bolus, infusion, 20 IU/kg per hour	Symptomatic proximal DVT	Parallel groups open (blind assessment) Europe
Prandoni sub-group , 1992 n=45/46 follow-up: 6 mo	Nadroparin, 47506650 antifactor Xa IU twice daily, 10 days versus Unfractioned heparin: bolus 100 IU/kg, infusion 35 000 IU/d	Symptomatic proximal DVT	Parallel groups open
Thery , 1992 n=35/33 follow-up: 14 d	Nadroparin, 76 IU/kg twice daily, 14 days versus Unfractioned heparin: bolus 50 IU/kg, infusion 600 IU/kg per day	patients with submassive pulmonary embolism	Parallel groups open

More details and results :

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

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5 superficial thrombophlebitis

Trial	Treatments	Patients	Trials design and methods
nadroparin fixed-dose vs nadroparin weight-adjusted			
Vesalio , 2005 n=NA follow-up:	LMWH (nadroparin) body-weight adjusted (full dose for 10 days followed by half dose for 20 additional days) versus nadroparin (2850 anti-Xa IU) for 30 days	patients with superficial vein thrombosis of the great saphenous vein with the thrombosis extending up to 3 cm from the sapheno-femoral junction	
nadroparin vs naproxene			
Titon (nadroparin 0.6ml vs naproxen) , 1994 n=NA follow-up:	nadroparin (s.c. 0.6 ml for 6150 IU anti-Xa once daily)j versus Naproxene (oral 500 mg once daily)	patients with ST	
Titon (nadroparin 61.5 IU anti-Xa/kg vs naproxen) , 1994 n=NA follow-up:	nadroparin (s.c. 0.6 ml for 6150 IU anti-Xa once daily)j versus Naproxene (oral 500 mg once daily)	patients with ST	

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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Titon (nadroparin 61.5 IU anti-Xa/kg vs naproxen), 1994:

Entry terms: fraxiparin, Nadroparin, Nadroparine, Nadroparin Calcium, Fraxiparin, Fraxiparine, CY 216, CY-216, CY216, LMF CY-216, LMF CY 216, LMF CY216, , Nadroparine, Fraxiparin, Fraxiparine, CY 216, CY-216, CY216, LMF CY-216, LMF CY 216, LMF CY216,