

# Clinical trials of Dalteparin

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## 1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>Dalteparin vs placebo</b>			
<b>BIOMACS II , 1999</b> n=54/47 follow-up: 1421 d	Dalteparin 100 mg/kg, 2 doses versus placebo	patients with acute myocardial infarction, Age <=80 y, STEMI or new LBBB	Parallel groups Double-blind
<b>FRAMI , 1997</b> n=388/388 follow-up: in hospital	65279;Dalteparin 150 mg/kg BID for 711 d versus placebo	65279;patients with an acute MI, Q wave or STEMI	Parallel groups 65279;Double-blind
<b>Dalteparin vs UFH</b>			
<b>ASSENT Plus , 2003</b> n=221/213 follow-up: 30 d	Dalteparin first dose 90 IU/kg, then 120 IU/kg BID, 47 d versus UFH 40005000 IU bolus, then 8001000 IU/h for 48 h	Patients with AMI treated with alteplase	Parallel groups open

More details and results :

- antithrombotics for acute myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q36>

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### **FRAMI, 1997:**

Kontny F, Dale J, Abildgaard U, Pedersen TR Randomized trial of low molecular weight heparin (dalteparin) in prevention of left ventricular thrombus formation and arterial embolism after acute anterior myocardial infarction: the Fragmin in Acute Myocardial Infarction (FRAMI) Study. *J Am Coll Cardiol* 1997;30:962-9 [[9316525](#)]

### **ASSENT Plus, 2003:**

Wallentin L, Bergstrand L, Dellborg M, Fellenius C, Granger CB, Lindahl B, Lins LE, Nilsson T, Pehrsson K, Siegbahn A, Swahn E Low molecular weight heparin (dalteparin) compared to unfractionated heparin as an adjunct to rt-PA (alteplase) for improvement of coronary artery patency in acute myocardial infarction-the

## 2 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
<b>dalteparin vs placebo (on top of aspirin)</b>			
<b>FRIC prolonged treatment phase (LWMH vs PBO) , 1997</b> n=731/751 follow-up: 45 days	dalteparin SC 120 i.u./kg twice-daily for 6 days followed by dalteparin 7500UI daily up to day 45 (+aspirin) versus unfractionated heparin dose-adjusted intravenous infusion (for at least 48h) then by subcutaneous injection up to day 6 (then placebo) (+aspirin)	Patients with unstable angina or non-Q-wave myocardial infarction	Parallel groups double blind
<b>FRISC (long term) , 1996</b> n=746/760 follow-up: 40 days	dalteparin SC 120 IU per kg bodyweight [maximum 10 000 IU] twice daily for 6 days with 7500 IU once daily for 34-45 days +aspirin versus matched placebo + aspirin	patients with unstable CAD (unstable angina or non-Q-wave myocardial infarction) within the previous 72 hours	Parallel groups double blind Sweden
<b>FRISC (short term) , 1996</b> n=746/760 follow-up: 6 days	dalteparin SC 120 IU per kg bodyweight [maximum 10 000 IU] twice daily for 6 days with 7500 IU once daily for 34-45 days +aspirin versus matched placebo + aspirin	patients with unstable CAD (unstable angina or non-Q-wave myocardial infarction) within the previous 72 hours	double blind Sweden
<b>dalteparin vs UFH (on top of aspirin)</b>			
<b>FRIC (acute phase LMWH vs UFH) , 1997</b> n=751/731 follow-up: 6 days	twice-daily weight-adjusted subcutaneous injections of dalteparin (120 i.u./kg) (+aspirin) versus dose-adjusted intravenous infusion of unfractionated heparin (+aspirin)	Patients with unstable angina or non-Q-wave myocardial infarction	open

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>

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Klein W, Buchwald A, Hillis SE, Monrad S, Sanz G, Turpie AG, van der Meer J, Olaisson E, Undeland S, Ludwig K Comparison of low-molecular-weight heparin with unfractionated heparin acutely and with placebo for 6 weeks in the management of unstable coronary artery disease. Fragmin in unstable coronary artery disease study (FRIC) Circulation 1997 Jul 1;96:61-8 [9236418]

### FRISC (long term), 1996:

Low-molecular-weight heparin during instability in coronary artery disease, Fragmin during Instability in Coronary Artery Disease (FRISC) study group. Lancet 1996;347:561-8 [8596317]

### FRISC (short term), 1996:

### FRIC (acute phase LMWH vs UFH), 1997:

Klein W, Buchwald A, Hillis SE, Monrad S, Sanz G, Turpie AG, van der Meer J, Olaisson E, Undeland S, Ludwig K Comparison of low-molecular-weight heparin with unfractionated heparin acutely and with placebo for 6 weeks in the management of unstable coronary artery disease. Fragmin in unstable coronary artery disease study (FRIC) Circulation 1997;96:61-8 [9236418]

## 3 DVT prophylaxis

Trial	Treatments	Patients	Trials design and methods
<b>dalteparin vs placebo</b>			
<b>D-KAf (Selby) , 2007</b> [NCT00187408] n=134/131 follow-up:	dalteparin 5000U daily versus placebo	below-knee fractures repaired surgically	
<b>Leizorovicz , 2004</b> n=1856/1850 follow-up: 21 days	Dalteparin 5000E once daily, 1' days versus placebo	Congestive heart failure (NYHA IIIIV), acute or chronic respiratory disease, infectious and rheumatologic disease	Parallel groups double blind
<b>Jorgensen , 1989</b> n=30/38 follow-up: 9 days	dalteparin 5000 x1 versus Placebo	Hip fracture	double blind
<b>Torholm , 1991</b> n=58/54 follow-up: 9 days	dalteparin 5000x1 versus Placebo	Elective hip	double blind
<b>Ockelford , 1989</b> n=102/95	Dalteparin 2500 anti-Xa units versus Placebo	general surgery	Blind

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
Lapidus , 2007 n=47/44 follow-up: 43 days	Dalteparin 5000 IU versus Placebo	patients surgically treated for Achilles tendon rupture	Parallel groups double-blind
Lapidus , 2007 n=101/96 follow-up: 44 days	Dalteparin 5000 IU versus Placebo	patients undergoing ankle fracture surgery	Parallel groups double-blind
<b>dalteparin vs Dextran</b>			
Matzsch , 1991 n=120/123	dalteparin versus Dextran	Elective hip	
Eriksson , 1988 n=50/50	dalteparin versus Dextran	Elective hip	
Matzsch , 1988 n=48/52	dalteparin versus Dextran	Elective hip	
<b>out of hospital Dalteparin vs standard prophylaxis</b>			
Dahl , 1997 n=134/131	65279;in hospital thromboprophylaxis followed by out of hospital Dalteparin 5000 IU once a day for a total duration of 35 days versus Dalteparin 5000 IU once a day for 7 days (dextran day 0 and day 1)	THR	
Lassen , 1998 n=140/141	65279;in hospital thromboprophylaxis followed by out of hospital Dalteparin 5000 IU once a day for a total duration of 35 days versus Dalteparin 5000 IU once a day for 7 days	THR	
Hull , 2000 n=389/180	65279;in hospital thromboprophylaxis followed by out of hospital Dalteparin 5000 IU once a day for a total duration of 35 days versus Dalteparin 5000 IU once a day or warfarin for 6 days	THR	
<b>dalteparin vs UFH</b>			

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>PROTECT , 2011</b> [NCT00182143] n=1873/1873 follow-up:	subcutaneous dalteparin 5000 IU once daily versus unfractionated heparin 5000 IU twice daily	critically ill patients	Parallel groups double-blind Canada, Australia, Brazil, Saudi Arabia, US, UK
<b>Scala , 1990</b> n=39 follow-up: 7 d	Dalteparin 120 IU/kg anti-Xa SC twice daily versus Standard heparin continuous IV infusion adapted to maintain aPTT between 1.5 and 2.5 times control value	acute myocardial infarction	Parallel groups open
<b>dalteparin vs Unfractionated heparin</b>			
<b>Binsack , 1986</b> n=48/47	dalteparin versus Unfractionated heparin	Elective hip	
<b>Briel , 1988</b> n=95/98 follow-up:	Dalteparin 5000 versus UFH 10 000 units+DHE	Gynaecological surgery	NA
<b>Barre , 1987</b> n=40/40	dalteparin versus Unfractionated heparin	Elective hip	
<b>Dechavanne , 1989</b> n=82/40	dalteparin versus Unfractionated heparin	Elective hip	
<b>Bergqvist , 1986</b> n=215/217 follow-up: 1 month	Dalteparin 5000 versus UFH 10 000 units	Abdominal surgery	Blind
<b>Onarheim , 1986</b> n=25/27 follow-up: 1 month	Dalteparin 5000 versus UFH 10 000 units	Abdominal surgery	Blind
<b>Eriksson , 1989</b> n=67/69	dalteparin versus Unfractionated heparin	Elective hip	
<b>Haas , 1985</b> n=65/65	dalteparin versus Unfractionated heparin	Elective hip	
<b>Koller , 1986</b> n=23/20 follow-up: 30 days	Dalteparin 7500 versus UFH 10 000 units	Abdominal surgery	Blind

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Koller , 1986</b> n=75/75 follow-up: 30 days	Dalteparin 2500 versus UFH 10 000 units	Abdominal surgery	Blind
<b>Fricker , 1988</b> n=40/40 follow-up: 1-2 months	Dalteparin 5000 versus UFH 15 000 units	Abdominopelvic surgery	Open
<b>Bergqvist , 1988</b> n=505/497 follow-up: 1 month	Dalteparin 5000 versus UFH 10 000 units	Abdominal surgery	Blind
<b>Caen , 1988</b> n=195/190 follow-up: 1 month	Dalteparin 2500 versus UFH 10 000 units	Abdominal surgery	Blind
<b>Borstad , 1988</b> n=105/110 follow-up:	Dalteparin 5000 versus UFH 10 000 units	Gynaecological surgery	Blind
<b>Monreal , 1989</b> n=46/44	dalteparin versus Unfractionated heparin	Hip	
<b>Creperio , 1990</b> n=20/20 follow-up:	Dalteparin 2500 versus UFH 10 000 units	General surgery	Blind
<b>Hartl , 1990</b> n=126/124 follow-up: >7 days	Dalteparin 2500 versus UFH 10 000 units	Abdominal surgery	Blind
<b>Borstad , 1992</b> n=77/75	Dalteparin 2500 anti Xa units versus UFH 10 000 units	Gynaecological surgery	Blind
<b>Kakkar , 1993</b> n=1894/1915	Dalteparin 2500 anti Xa units versus UFH 10 000 units	Abdominal 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 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 gynaecological surgery at <http://www.trialresultscenter.org/go-Q94>
- antithrombotics for DVT prophylaxis in abdominal surgery at <http://www.trialresultscenter.org/go-Q96>
- 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>
- 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>
- antithrombotics for DVT prophylaxis in patients with immobilization of the lower extremities at <http://www.trialresultscenter.org/go-Q405>
- antithrombotics for DVT prophylaxis in patients with myocardial infarction at <http://www.trialresultscenter.org/go-Q406>

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## 4 venous thrombosis

Trial	Treatments	Patients	Trials design and methods
<b>extended dalteparin vs standard treatment</b>			
Lee , 2003 n=NA follow-up: 6 months	Dalteparin 200 IU/kg daily for 1 month followed by 150 IU/kg daily for 5 months versus Dalteparin 200 IU/kg daily for 5-7 days followed by warfarin or acecumarol (target INR 2-3) for 6 months	patients with active cancer and with DVT or pulmonary embolism or both, and ECOG 1 or 2	Parallel groups outcome assessment blinded
<b>Dalteparin vs warfarin</b>			
Lee , 2003 n=336/336 follow-up: 6 mo	LMWH, 200 IU/kg qd followed by Dalteparin 150 IU/kg qd versus LMWH, 200 IU/kg qd followed by Warfarin target INR 2-3	patients with cancer and objective diagnosis of DVT by Venography/compression ultrasonography	open
Das , 1996 n=50/55 follow-up: 3 mo	UFH followed by Dalteparin 5,000 IU qd versus UFH followed by Warfarin target INR 2-3	patients with objective diagnosis of DVT by Venography	open
<b>once daily dalteparin vs twice daily dalteparin</b>			
Holmstrm , 1992 n=50/51 follow-up:	once daily dalteparin 200 U (anti-FXa)/kg for at least 5 days versus twice daily dalteparin 100 U (anti-FXa)/kg for at least 5 days	Patients with a first occurrence of DVT in the lower limb, confirmed with phlebography	Parallel groups open Sweden
Partsch , 1996 n=76/64 follow-up:	Fragmin administered 200 IU/kg once daily for at least 7 days versus Fragmin 100 IU/kg twice daily for at least 7 days	patients presented with DVT extending into the iliofemoral segment diagnosed by duplex ultrasonography	Parallel groups NA Austria
<b>Dalteparin vs unfractionated heparin</b>			
Holm et al , 1986 n=29/27 follow-up: Hospital Stay	Dalteparin Subcutaneous twice daily adjusted for 7 Days, 57-107 U/kg BID versus unfractionated heparin subcutaneous twice daily 16000-30000 U	-	

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Trial	Treatments	Patients	Trials design and methods
Bratt et al , 1985 n=25/29 follow-up: 23 Months (mean)	Dalteparin Intravenous (adjusted) for >=5 Days, 120 U/kg BID versus unfractionated heparin intravenous APPTx1.7-3.5	-	
Bratt et al , 1990 n=60/60 follow-up: 65279;Hospital stay	Dalteparin Subcutaneous twice daily adjusted for >= 5 Days, 120 U/kg BID versus unfractionated heparin intravenous APPTx2-4	-	
Lindmarker et al , 1993 n=101/103 follow-up: 6 Months	Dalteparin Subcutaneous once daily for >= 5 Days, 200 U/kg BID versus unfractionated heparin intravenous APPTx1.5-3	-	

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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## 5 percutaneous coronary intervention

12

Trial	Treatments	Patients	Trials design and methods
<b>dalteparin vs UFH</b>			
<a href="#">Natarajan (without antiGp2b3a) , 2003</a> n=NA follow-up:	Dalteparin 100 IU/kg bolus versus UFH 100 IU/kg bolus	Elective or urgent PCI	
<b>dalteparin vs UFH + anti Gp2b3a</b>			
<a href="#">Natarajan (+ antiGp2b3a) , 2003</a> n=NA	Dalteparin 70 IU/kg bolus + GP IIb/IIIa inhibitors/p versus 65279;UFH 70 IU/kg bolus +GPIIb/IIIa inhibitors	-	

More details and results :

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

## References

### Natarajan (without antiGp2b3a), 2003:

NatarajanMK, Turpie GA, Raco DL, Velianon JL, Mehta SR, Afzal A randomized comparison of dalteparin versus unfractionated heparin during percutaneous coronary interventions. J Am Coll Cardiol 2003;41(Suppl A):68A69A.xtPag

### Natarajan (+ antiGp2b3a), 2003:

## 6 pulmonary embolism

Trial	Treatments	Patients	Trials design and methods
<b>Dalteparin vs unfractionated heparin</b>			
<b>Kuijer , 1995</b> n=32/35 follow-up: 3 mo	Dalteparin, 120 IU/kg twice daily, 5 days versus Unfractionated heparin: bolus 5000 IU, infusion 1250 IU/h	Symptomatic PE	Parallel groups open
<b>Meyer , 1995</b> n=29/31 follow-up: 3 mo	Dalteparin, 120 IU/kg twice daily, 10 days versus Unfractionated heparin: no bolus, infusion 500 IU/kg per day	Symptomatic PE	Parallel groups open

More details and results :

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

## References

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Kuijer PM, Gallus AS, Cade JE, Buller HR. /jpeg Randomized comparison of LMWH versus standard heparin in the initial treatment of pulmonary embolism [Abstract]. Thromb Haemost. 1995;73:974

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Meyer G, Brenot F, Pacouret G, Simonneau G, Gillet Juvin K, Charbonnier B, Sors H Subcutaneous low-molecular-weight heparin fragmin versus intravenous unfractionated heparin in the treatment of acute non massive pulmonary embolism: an open randomized pilot study. Thromb Haemost 1995;74:1432-5 [8772215]

Entry terms: dalteparin