Clinical trials of heparin (UFH or LMWH) for acute coronary syndrome in all type of patients

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1 long term LMWH

Trial	Treatments	Patients	Trials design and methods
dalteparin vs placebo (on top of aspirin)			
FRIC prolonged treatment phase (LWMH vs PBO) , 1997 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
FRISC (long term) , 1996 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
FRISC (short term) , 1996 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
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

continued...

Trial	Treatments	Patients	Trials design and methods
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
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,
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

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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:

ESSENCE, 1997:

Cohen M, Demers C, Gurfinkel EP, Turpie AG, Fromell GJ, Goodman S, Langer A, Califf RM, Fox KA, Premmereur J, Bigonzi F A comparison of low-molecular-weight heparin with unfractionated heparin for unstable coronary artery disease. Efficacy and Safety of Subcutaneous Enoxaparin in Non-Q-Wave Coronary Events Study Group. N Engl J Med 1997;337:447-52 [9250846] 10.1056/NEJM199708143370702

INTERACT, 2006:

Fitchett DH, Langer A, Armstrong PW, Tan M, Mendelsohn A, Goodman SG Randomized evaluation of the efficacy of enoxaparin versus unfractionated heparin in high-risk patients with non-ST-segment elevation acute coronary syndromes receiving the glycoprotein IIb/IIIa inhibitor eptifibatide. Long-term results of the Integrilin and Enoxaparin Randomized Assessment of Acute Coronary Syndrome Treatment (INTERACT) trial. Am Heart J 2006;151:373-9 [16442903]

Goodman SG, Fitchett D, Armstrong PW, Tan M, Langer A Randomized evaluation of the safety and efficacy of enoxaparin versus unfractionated heparin in high-risk patients with non-ST-segment elevation acute coronary syndromes receiving the glycoprotein IIb/IIIa inhibitor eptifibatide. Circulation 2003;107:238-44 [12538422]

SYNERGY, 2005:

Mahaffey KW, Cohen M, Garg J, Antman E, Kleiman NS, Goodman SG, Berdan LG, Reist CJ, Langer A, White HD, Aylward PE, Col JJ, Ferguson JJ 3rd, Califf RM High-risk patients with acute coronary syndromes treated with low-molecular-weight or unfractionated heparin: outcomes at 6 months and 1 year in the SYNERGY trial. JAMA 2005 Nov 23;294:2594-600 [16304073]

White HD, Kleiman NS, Mahaffey KW, Lokhnygina Y, Pieper KS, Chiswell K, Cohen M, Harrington RA, Chew DP, Petersen JL, Berdan LG, Aylward PE, Nessel CC, Ferguson JJ 3rd, Califf RM Efficacy and safety of enoxaparin compared with unfractionated heparin in high-risk patients with non-ST-segment elevation acute coronary syndrome undergoing percutaneous coronary intervention in the Superior Yield of the New Strategy of Enoxaparin, Revascularization and Glycoprotein IIb/IIIa Inhibitors (SYNERGY) trial. Am Heart J 2006;152:1042-50 [17161049]

Ferguson JJ, Califf RM, Antman EM, Cohen M, Grines CL, Goodman S, Kereiakes DJ, Langer A, Mahaffey KW, Nessel CC, Armstrong PW, Avezum A, Aylward P, Becker RC, Biasucci L, Borzak S, Col J, Frey MJ, Fry E, Gulba DC, Guneri S, Gurfinkel E, Harrington R, Hoc Enoxaparin vs unfractionated heparin in high-risk patients with non-ST-segment elevation acute coronary syndromes managed with an intended early invasive strategy: primary results of the SYNERGY randomized trial. JAMA 2004;292:45-54 [15238590]

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TIMI 11 B (short term), 1998:

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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 short term LMWH

Trial	Treatments	Patients	Trials design and methods
dalteparin vs placebo (on top of aspirin)			
FRIC prolonged treatment phase (LWMH vs PBO) , 1997 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
FRISC (long term) , 1996 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

continued...

Trial	Treatments	Patients	Trials design and methods
FRISC (short term) , 1996 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
LMWH vs placebo (on top of aspirin)			
Gurfinkel (LMWH+asp vs asp) , 1995 n=68/73 follow-up: 5-7 days	aspirin plus low molecular weight heparin (214 UIC/kg anti-Xa twice daily subcutaneously versus aspirin (200 mg/day	patients with unstable angina	Parallel groups single blind
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
dalteparin vs UFH (on top of aspirin)			
FRIC (acute phase LMWH vs UFH) , 1997 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
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

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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,
LMWH vs UFH (on top of aspirin)			
Gurfinkel (LMWH+asp vs UFH+asp) , 1995 n=68/70 follow-up: 5-7 days	aspirin plus low molecular weight heparin (214 UIC/kg anti-Xa twice daily subcutaneously versus aspirin plus regular heparin (400 IU/kg body weight per day intravenously and titered by activated partial thromboplastin time	patients with unstable angina	Parallel groups single blind
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

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Gurfinkel EP, Manos EJ, Mejal RI, Cerd MA, Duronto EA, Garca CN, Daroca AM, Mautner B Low molecular weight heparin versus regular heparin or aspirin in the treatment of unstable angina and silent ischemia. J Am Coll Cardiol 1995 Aug;26:313-8 [7608429]

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Ferguson JJ, Califf RM, Antman EM, Cohen M, Grines CL, Goodman S, Kereiakes DJ, Langer A, Mahaffey KW, Nessel CC, Armstrong PW, Avezum A, Aylward P, Becker RC, Biasucci L, Borzak S, Col J, Frey MJ, Fry E, Gulba DC, Guneri S, Gurfinkel E, Harrington R, Hoc Enoxaparin vs unfractionated heparin in high-risk patients with non-ST-segment elevation acute coronary syndromes managed with an intended early invasive strategy: primary results of the SYNERGY randomized trial. JAMA 2004;292:45-54 [15238590]

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3 short term UFH

Trial	Treatments	Patients	Trials design and methods
UFH vs control (on top of aspirin)			
Holdright , 1994 n=154/131 follow-up: hospital stay	intravenous heparin plus oral aspirin (150 mg once daily) versus aspirin alone 150 mg/d	unstable angina	Parallel groups single blind
RISC (heparin+aspirin vs ASP) , 1990 n=210/189 follow-up: 90 days	5 days of intermittent intravenous heparin + oral aspirin 75 mg/day versus oral aspirin 75 mg/day	unstable angina or non-Q-wave myocardial infarction	Parallel groups open
Theroux (heparin+ASP vs ASP) , 1988 n=122/121 follow-up: 3-9 days	aspirin 325 mg/d + heparin 1000 UI/hr IV versus aspirin 325 mg/d		double blind
UFH, warfarin vs control (on top of aspirin)			
ATACS (Cohen) , 1994 n=105/109 follow-up: 12 weeks	aspirin 162.5 mg daily plus heparin (activated partial thromboplastin time, two times control) followed by aspirin 162.5 mg daily plus warfarin (international normalized ratio, 2 to 3) for 12 weeks. versus aspirin alone (162.5 mg daily) for 12 weeks.	patients with unstable rest angina or non-Q-wave myocardial infarction with last episode of pain within 48 hours of randomization and who were nonprior aspirin users	Parallel groups single blind
Cohen (ATACS pilot) (heparin+aspirin vs asp) , 1990 n=37/32 follow-up: 12 weeks	aspirin (80 mg/day) plus heparin and then warfarin versus aspirin (325 mg/day)	Patients between 21 and 75 years with unstable angina or non-Q-wave MI with last episode of pain within 48 hours of screening.	Parallel groups open
UFH vs placebo			
RISC (heparin vs PBO) , 1990 n=198/199 follow-up: 1y (5,30 and 90 days)	5 days of intermittent intravenous heparin versus placebo	men with unstable coronary artery disease (unstable angina or non-Q-wave myocardial infarction)	Factorial plan Sweden
Theroux (heparin vs PBO) , 1988 n=118/118 follow-up: 3-9 days	heparin (1000 units per hour by intravenous infusion) versus placebo	patients with acute unstable angina pectoris	double blind
UFH + aspirin vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
RISC (ASP+ heparin vs PBO) , 1990 n=210/199 follow-up: 1y (5,30 and 90 days)	oral apsirin 75mg/d + intermittent IV heparin 10000UI/d followed by 7500 UI 6-hourly for 4 days versus placebo	men with unstable coronary artery disease (unstable angina or non-Q-wave myocardial infarction)	Sweden
Theroux (heparin+aspirin vs PBO) , 1988 n=122/118 follow-up: 3-9 days	heparin (1000 units per hour by intravenous infusion)+ aspirin (325 mg twice daily) versus aspirin (325 mg twice daily)	-	double blind
UFH vs placebo (on top of aspirin)			
Gurfinkel (UFH+aspririn vs aspirin) , 1995 n=70/73 follow-up: 5-7 days	aspirin plus UFH 5000 IU iv then 400 IU/kg body weight per day intravenously and titered by activated partial thromboplastin time versus aspirin 200 mg/day	patients greater than 21 years with ustable angina within 24 hours of randomizationcatio	Parallel groups double blind
UFH, warfarin vs aspirin			
Cohen (ATACS pilot) (heparin vs asp) , 1990 n=24/32 follow-up: 12 weeks	heparin followed by warfarin (without aspirin) versus aspirin 325 mg/day	Patients between 21 and 75 years with unstable angina or non-Q-wave MI with last episode of pain within 48 hours of screening	Parallel groups open

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RISC (heparin+aspirin vs ASP), 1990:

Risk of myocardial infarction and death during treatment with low dose aspirin and intravenous heparin in men with unstable coronary artery disease. The RISC Group. Lancet 1990;336:827-30 [1976875]

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Cohen M, Adams PC, Parry G, Xiong J, Chamberlain D, Wieczorek I, Fox KA, Chesebro JH, Strain J, Keller C Combination antithrombotic therapy in unstable rest angina and non-Q-wave infarction in nonprior aspirin users. Primary end points analysis from the ATACS trial. Antithrombotic Therapy in Acute Coronary Syndromes Research Group. Circulation 1994;89:81-8 [8281698]

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Throux P, Ouimet H, McCans J, Latour JG, Joly P, Lvy G, Pelletier E, Juneau M, Stasiak J, deGuise P Aspirin, heparin, or both to treat acute unstable angina. N Engl J Med 1988;319:1105-11 [3050522]

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4 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

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