

Clinical trials of antithrombotics for acute myocardial infarction in all type of patients

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1 direct thrombin inhibitor

Trial	Treatments	Patients	Trials design and methods
Argatroban vs heparin			
ARGAMI-2 , 1998 n=NA follow-up: 30 days	Argatroban 6020 mg/kg bolus; 24 g /kg/min infusion for 72h versus UFH 5000 IU bolus; 1000 IU/h infusion	AMI	
bivalirudin vs heparin			
HERO , 1997 n=272/140 follow-up: 35 days	Bivalirudin 0.1250.250 mg/kg bolus; 0.1250.500 mg /kg/min infusion for 72h versus UFH 5000 IU bolus; 10001200 IU/h infusion	AMI (patients presenting within 12 hours with ST-segment elevation)	Parallel groups double blind
Hirudin vs heparin			
HIT-4 , 1999 n=447 follow-up: 30 days	Hirudin 0.2 mg/kg bolus; 0.5 mg/kg twice daily 0.1 mg/kg 0.1 mg /kg/h infusion for 5-7 days versus Placebo bolus, UFH 12 500 IU twice daily	patients with AMI <=6 h were treated with aspirin and streptokinase	Parallel groups double blind
TIMI 9B , 1996 n=3002 follow-up: 30 days	Hirudin 0.1 mg/kg bolus; 0.1 mg /kg/h infusion for 96h versus UFH 5000 IU bolus; 1000 IU/h infusion	Unstable angina or AMI	Parallel groups open

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2 Low molecular weight heparin

Trial	Treatments	Patients	Trials design and methods
Dalteparin vs placebo			
BIOMACS II , 1999 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
FRAMI , 1997 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
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
Reviparin vs placebo			
CREATE , 2005 n=7780/7790 follow-up: 30 d	Reviparin 34366871 IU BID for 7 d (weight adjusted) versus placebo	patients with acute myocardial infarction, STEMI or new LBBB, <=12 h	Parallel groups Double-blind
Dalteparin vs UFH			
ASSENT Plus , 2003 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
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

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Trial	Treatments	Patients	Trials design and methods
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

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3 oral anticoagulant

Trial	Treatments	Patients	Trials design and methods
coumadin vs control (on top of aspirin)			
ASPECT-2 (coumadin+ASA vs ASA) , 2002 n=298/289 follow-up: 1 year	coumadin(INR mean 2.4) +aspirin versus aspirin	Acute MI, unstable angina	Parallel groups open the Netherlands
warfarin vs control (on top of aspirin)			
WARIS , 1999 n=1208/1206 follow-up: 65279;37 months	warfarin 2.84.8 versus placebo	survivors of acute myocardial infarction	Parallel groups double blind
APRICOT-2 , 2002 n=135/139 follow-up: 3 months	moderate-intensity coumarin target INR 2-3 (+aspirin) versus aspirin	Acute MI after thrombolytics	Parallel groups open the Netherlands
CARS (warafarin 3mg) , 1997 n=5410/3393 follow-up: 14 months	warfarin fixed dose 3mg/d + 80 mg ASA versus aspirin 160 mg/d	AMI	Parallel groups double blind North America
CARS (warfarin 1mg) , 1997 n=2028/3393 follow-up: 14 months	warfarin 1mg/d + aspirin 80mg/d versus aspirin 160 mg/d	patients who had had myocardial infarction	Parallel groups double blind North America
CHAMP , 2002 n=2522/2537 follow-up: 2.7 years	warfarin target INR 1.5-2.5 + aspirin 81 mg daily versus aspirin 162 mg/d	AMI (patients enrolled within 14 days of infarction)	Parallel groups open US
LoWASA , 2004 n=1659/1641 follow-up: 5 years	warfarin fixed dose 1.25mg/d + ASA 75mg/d versus aspirin alone	AMI	Parallel groups open Sweden
WARIS II (warfarin+ASA) , 2002 n=4927/4669 follow-up: 4 years	warfarin target INR 2-2.5 +ASA 75mg/d versus ASA 160mg/d	patients hospitalized for acute myocardial infarction	Parallel groups open Norway
Zibaenezhad , 2004 n=70/70 follow-up: 1 year	Warfarin target INR 65279;23 +aspirin versus aspirin 100 mg/day	Acute MI	Parallel groups open

continued...

Trial	Treatments	Patients	Trials design and methods
any anticoagulant vs placebo			
Sixty Plus reinfarction Study , 1980 n=NA follow-up: 2 years	anticoagulant versus placebo	over 60 years of age	Parallel groups double blind
coumadin vs placebo			
ASPECT , 1994 n=1700/1704 follow-up: 37 months (range 6-76)	nicoumalone or phenprocoumon, target INR 2.84.8 versus placebo	hospital survivors of myocardial infarction	Parallel groups double blind
phenprocoumon vs placebo			
German-Austrian Study Group (oac vs pbo) , 1980 n=320/309 follow-up: 2 years	phenprocoumon versus placebo	patients who had survived a myocardial infarction for 30-42 days	Parallel groups double blind
warfarin vs placebo (on top of aspirin)			
Williams , 1997 n=6/5 follow-up: 2.5 months	warfarin target INR 65279;22.5 +aspirin versus placebo +aspirin	Acute MI, unstable angina	Parallel groups double blind
any anticoagulant vs aspirin			
EPSIM , 1982 n=652/651 follow-up: 29 months (range 6-59)	anticoagulant versus aspirin 500mg three times daily	patients surviving myocardial infarction	Parallel groups open
coumadin vs aspirin			
ASPECT-2 (coumadin alone) , 2002 n=325/336 follow-up: 1 year (range 0-26 months)	coumadin (phenprocoumon or acenocoumarol) target INR 3-4 versus aspirin 80mg daily	Acute MI, unstable angina	Parallel groups open the Netherlands
phenprocoumon vs aspirin			
German-Austrian Study Group (oac vs asp) , 1980 n=320/317 follow-up: 2 years	phenprocoumon versus aspirin 1.5 g daily	patients who had survived a myocardial infarction for 30-42 days	Parallel groups double blind
warfarin vs aspirin			
WARIS II (warfarin alone) , 2002 n=1216/1206 follow-up: 48 months	warfarin target INR 2.8-4.2 versus ASA 160mg/d	patients hospitalized for acute myocardial infarction	Parallel groups NA Norway

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4 pentasccharide

Trial	Treatments	Patients	Trials design and methods
fondaparinux vs placebo			
MICHELANGELO OASIS-6 , 2006 [NCT00064428] n=6036/6056 follow-up: 30 days	fondaparinux 2.5 mg once daily up to 8 days versus control (UFH or placebo)	patients with STEMI	Factorial plan double-blind 41 countries

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5 unfractionated heparin

Trial	Treatments	Patients	Trials design and methods
UFH vs no heparin			
ISIS-2 Pilot , 1987 n=106/103 follow-up: 65279;In-hospital, 1 y (deat	UFH nNo bolus, 1000 IU/h for 48 h versus 65279;No heparin	patients with s65279;uspected MI <=24 h	Parallel groups open
DUCCS , 1994 n=128/122 follow-up: 14 d	UFH no bolus, 15 IU/kg per h for 4 d; target aPTT 5090 s versus No heparin	patients with acute myocardial infarction four hours after APSAC administration, age <=85 y STEMI <=12 h	Parallel groups open
UFH vs placebo			
ECSSG , 1992 n=324/320 follow-up: In-hospital	UFH 5000 IU bolus, UFH 1000 IU/h for 48120 h versus Placebo	patients treated with alteplase thrombolysis for acute myocardial infarction, Age 2170 y STEMI <=6h	Parallel groups Double-blind

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Trial	Treatments	Patients	Trials design and methods
OSIRIS , 1992 n=64/64 follow-up: In-hospital	UFH 10 000 IU bolus, 1000 IU/h for 24 h versus Placebo	STEMI w=6 h	Parallel groups Double-blind

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6 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.

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