

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 (warfarin 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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