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



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# 2 Low molecular weight heparin

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **Dalteparin vs placebo** | | | |
| BIOMACS II , 1999<br>n=54/47<br>follow-up: 1421 d | Dalteparin 100 mg/kg, 2 doses<br>versus<br>placebo | patients with acute myocardial infarction, Age <=80 y, STEMI or new LBBB | Parallel groups<br>Double-blind |
| FRAMI , 1997<br>n=388/388<br>follow-up: in hospital | 65279;Dalteparin 150 mg/kg BID for 711 d<br>versus<br>placebo | 65279;patients with an acute MI, Q wave or STEMI | Parallel groups<br>65279;Double-blind |
| **Enoxaparin vs placebo** | | | |
| AMI-SK , 2002<br>n=253/243<br>follow-up: 30 d | Enoxaparin 30 mg IV bolus, 1 mg/kg for 38 d<br>versus<br>placebo | patients with evolving myocardial infarction, Age >=18 y, STEMI | Parallel groups<br>Double-blind |
| **Reviparin vs placebo** | | | |
| CREATE , 2005<br>n=7780/7790<br>follow-up: 30 d | Reviparin 34366871 IU BID for 7 d (weight adjusted)<br>versus<br>placebo | patients with acute myocardial infarction, STEMI or new LBBB, <=12 h | Parallel groups<br>Double-blind |
| **Dalteparin vs UFH** | | | |
| ASSENT Plus , 2003<br>n=221/213<br>follow-up: 30 d | Dalteparin first dose 90 IU/kg, then 120 IU/kg BID, 47 d<br>versus<br>UFH 40005000 IU bolus, then 8001000 IU/h for 48 h | Patients with AMI treated with alteplase | Parallel groups<br>open |
| **Enoxaparin vs UFH** | | | |
| ASSENT 3 Plus , 2003<br>n=818/821<br>follow-up: 30 d | Enoxaparin 1 mg/kg BID, <=7d<br>versus<br>UFH 60 IU/kg, then 12 IU/kg per h for >=3d | patients with ST-elevation myocardial infarction | Parallel groups<br>open |
| ASSENT 3 , 2001<br>n=2040/2038<br>follow-up: 65279;30 d | 65279;Enoxaparin 1 mg/kg BID, <=7d<br>versus<br>UFH 65279;60 U/kg bolus, then 12 IU/kg per h for 48 h | patients with acute myocardial infarction | Parallel groups<br>open |
| Baird , 2002<br>n=149/151<br>follow-up: 90 d | Enoxaparin 40 mg TID, 4 d<br>versus<br>UFH 5000 IU bolus, then 30 000 IU over 24 h for 4d | patients receiving fibrinolytic therapy following acute myocardial infarction | Parallel groups<br>90-min TIMI flow |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| ENTIRE-TIMI 2 , 2002<br>n=160/82<br>follow-up: 30 d | Enoxaparin 1 mg/kg BID, <=8d<br>versus<br>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<br>open |
| HART II , 2001<br>n=200/200<br>follow-up: 57 d | Enoxaparin 1 mg/kg BID, <=3d<br>versus<br>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<br>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<br>n=298/289<br>follow-up: 1 year | coumadin(INR mean 2.4) +aspirin<br>versus<br>aspirin | Acute MI, unstable angina | Parallel groups<br>open<br>the Netherlands |
| **warfarin vs control (on top of aspirin)** | | | |
| WARIS , 1999<br>n=1208/1206<br>follow-up: 65279;37 months | warfarin 2.84.8<br>versus<br>placebo | survivors of acute myocardial infarction | Parallel groups<br>double blind |
| APRICOT-2 , 2002<br>n=135/139<br>follow-up: 3 months | moderate-intensity coumarin target INR 2-3 (+aspirin)<br>versus<br>aspirin | Acute MI after thrombolytics | Parallel groups<br>open<br>the Netherlands |
| CARS (warafrin 3mg) , 1997<br>n=5410/3393<br>follow-up: 14 months | warfarin fixed dose 3mg/d + 80 mg ASA<br>versus<br>aspirin 160 mg/d | AMI | Parallel groups<br>double blind<br>North America |
| CARS (warfarin 1mg) , 1997<br>n=2028/3393<br>follow-up: 14 months | warfarin 1mg/d + aspirin 80mg/d<br>versus<br>aspirin 160 mg/d | patients who had had myocardial infarction | Parallel groups<br>double blind<br>North America |
| CHAMP , 2002<br>n=2522/2537<br>follow-up: 2.7 years | warfarin target INR 1.5-2.5 + aspirin 81 mg daily<br>versus<br>aspirin 162 mg/d | AMI (patients enrolled within 14 days of infarction) | Parallel groups<br>open<br>US |
| LoWASA , 2004<br>n=1659/1641<br>follow-up: 5 years | warfarin fixed dose 1.25mg/d + ASA 75mg/d<br>versus<br>aspirin alone | AMI | Parallel groups<br>open<br>Sweden |
| WARIS II (warfarin+ASA) , 2002<br>n=4927/4669<br>follow-up: 4 years | warfarin target INR 2-2.5 +ASA 75mg/d<br>versus<br>ASA 160mg/d | patients hospitalized for acute myocardial infarction | Parallel groups<br>open<br>Norway |
| Zibaeenezhad , 2004<br>n=70/70<br>follow-up: 1 year | Warfarin target INR 65279;23 +aspirin<br>versus<br>aspirin 100 mg/day | Acute MI | Parallel groups<br>open |

continued...

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



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# 4 pentasccharide

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

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# 5 unfractionated heparin

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

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

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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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