Clinical trials of antithrombotics for percutaneous coronary intervention in all type of patients

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1 antiplatelet drugs

Trial	Treatments	Patients	Trials design and methods
vs placebo			
Finci , 1989 n=54/53 follow-up: 6m	-	-	Parallel groups
Oriol , 1995 n=171/171 follow-up: 6m	-	-	Parallel groups
aspirin vs placebo			
Taylor (Perth) , 1991 n=124/128 follow-up: 6m	aspirin, 100 mg/day after 2 weeks versus placebo	patients aged less than 70 years without acute infarction undergoing PTCA	Parallel groups double blind
M-HEART II (aspirin) , 1995 n=497/510 follow-up: 6m	aspirin 325 mg daily versus placebo	patients undergoing PTCA	Parallel groups double blind
aspirin + dipyridamol vs placebo			
Schwartz (Toronto) , 1988 n=187/189 follow-up: 6m	aspirin 990 + D225 (H) versus placebo	-	Parallel groups double blind Canada
White (aspirin+dipiridamol) , 1991 n=245/254 follow-up: 6m	-	-	Parallel groups
Nye (Dunedin) , 1990 n=35/37 follow-up: 12m	aspirin 300 + D225 versus placebo	-	Parallel groups NA
Mayo-PTCA , 1989 n=102/105 follow-up: 48h	-	-	Parallel groups
sulotroban vs placebo			
M-HEART II (sulotroban) , 1995 n=752 follow-up: 6 months	-	patients undergoing PTCA	Parallel groups double blind
ticlopidine vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
White (ticlopidine) , 1991 n=NA follow-up: 6m	ticlopidine 500, aspirin 650 + D225 versus placebo	-	Parallel groups
TACT , 1990 n=177/173 follow-up: 6m	-	-	Parallel groups

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2 competitive PAR-1 antagonist

Trial	Treatments	Patients	Trials design and methods
SCH 530348 vs placebo			
TRA-PCI , 2009 [NCT00132912] n=NA follow-up:	SCH 530348 3 doses: 10mg, 20mg and 40mg versus placebo	patients aged 45 years or older and undergoing non-urgent PCI or coronary angiography with planned PCI	Parallel groups double-blind

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3 direct thrombin inhibitor

Trial	Treatments	Patients	Trials design and methods
bivalirudin vs heparin + GP2b3a inhibitors			
ACUITY (Stone) (bivalirudin alone) , 2006 [NCT00093158] n=9216/4603 follow-up: 30 days	bivalirudin alone versus unfractionated heparin or enoxaparin plus a glycoprotein IIb/IIIa inhibitor	patients with acute coronary syndromes	Parallel groups open
HORIZONS-AMI (Stone) , 2008 [NCT00433966] n=1800/1802 follow-up: 30 days	Bivalirudin versus Heparin plus GP IIb/IIIa inhibitor	patients with ST-segment elevation myocardial infarction who presented within 12 hours after the onset of symptoms and who were undergoing primary PCI	Parallel groups open 11 countries
REPLACE-2 , 2003 n=2994/3008 follow-up: 30 days	bivalirudin, with glycoprotein IIb/IIIa (Gp IIb/IIIa) inhibition on a provisional basis for complications during PCI versus heparin plus planned Gp IIb/IIIa blockade	patients undergoing urgent or elective PCI	Parallel groups double blind 9 countries
bivalirudin + eptifibatide vs heparin + GP2b3a inhibitors			
Kleiman , 2002 n=NA follow-up:	bivalirudin + eptifibatide versus heparin + eptifibatide	patients who underwent elective percutaneous coronary intervention	Parallel groups open
bivalirudin vs UFH			

continued...

Trial	Treatments	Patients	Trials design and methods
ARMYDA BIVALVE n=140 follow-up:	bivalirudin (0.75 mg/kg bolus followed by 1.75 mg/kg per hour during the procedure) versus unfractionated heparin (75 IU/kg)	patients at high bleeding risk (over 75 years of age, diabetes, reduced renal function) scheduled for PCI	Parallel groups
BAT (Bittl) , 1995 n=2059/2039 follow-up: hospital stay	bivalirudin immediately before angioplasty. versus heparin immediately before angioplasty	patients undergoing urgent angioplasty for unstable or postinfarction angina	Parallel groups double blind US
ISAR-REACT 3 , 2008 [NCT00262054] n=2289/2281 follow-up: 30 days (mean)	UFH bolus of 140 U/kg versus bivalirudin (bolus of 0.75 mg/kg, followed by infusion of 1.75 mg/kg/hr)	troponin-negative patients undergoing PCI	Parallel groups double blind
REPLACE-1 , 2004 n=532/524 follow-up: hospital stay (48h min)	bivalirudin (0.75 mg/kg bolus, 1.75 mg/kg/h infusion during the procedure versus heparin (70 U/kg initial bolus) adjusted to ACT of 200 to 300s	patients undergoing elective or urgent revascularization	Parallel groups US
bivalirudin vs UFH plus tirofiban			
NAPLES (Tavano) , 2009 n=167/168 follow-up: 30 days	bivalirudin monotherapy versus unfractionated heparin plus tirofiban	patients with diabetes mellitus undergoing elective percutaneous coronary intervention	Parallel groups open Italy

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4 fondaparinux

Trial	Treatments	Patients	Trials design and methods
fondaparinux vs unfractionated heparin or bivalirudin			
SWITCH III *ongoing* [NCT00464087] n=NA follow-up:	fondaparinux versus unfractionated heparin or bivalirudin	patients experiencing acute coronary syndrome undergoing percutaneous coronary angioplasty	Parallel groups open

References

SWITCH III, :

5 GP IIaIIIb inhibitors

Trial	Treatments	Patients	Trials design and methods
vs			
IMPACT (12h) , 1993 n=NA	-	-	
EPIC (without infusion) , 1991 n=NA	-	-	
IMPACT-II (0.75g) , 1994 n=NA	-	-	
Abciximab vs placebo			
ADMIRAL , 2001 n=NA	-	Primary PCI	
CADILLAC , 2002 n=NA	-	Primary PCI	
RAPPORT , 1998 n=NA	-	Primary PTCA <	
EPIC (with infusion) , 1994 n=NA	-	High risk for abrupt closurebitm	
EPILOG , 1997 n=NA	-	Elective or urgent PCIe	
EPISTENT , 1998 n=NA	-	Elective or urgent PCI	
CAPTURE , 1997 n=NA	-	-	
ERASER , 1999 n=NA	-	-	
Petronio , 2002 n=NA	-	-	
Simoons , 1994 n=NA	-	-	
Kini , 2001 n=NA	-	-	
Tamburino , 2002 n=NA	-	-	
ISAR-2 , 2000 n=NA	-	PCI <48 h after MI	
Eptifibatide vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
ESPRIT , 2000 n=NA	-	Nonurgent PCI	
IMPACT (4h) , 1995 n=NA	-	Elective PCI	
IMPACT-II (0.5g) , 1997 n=NA	-	Any PCI	
Harrington , 1995 n=NA	-	-	
Tirofiban vs placebo			
RESTORE , 1997 n=NA	-	PCI <72 h after USA or MI	
Kereiakis , 1996 n=NA	-	-	

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EPIC (without infusion), 1991:

IMPACT-II (0.75g), 1994:

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6 Low Molecular Weight Heparin

Trial	Treatments	Patients	Trials design and methods
dalteparin vs UFH			
Natarajan (without antiGp2b3a) , 2003 n=NA follow-up:	Dalteparin 100 IU/kg bolus versus UFH 100 IU/kg bolus	Elective or urgent PCI	
enoxaparin vs UFH			
ATOLL , 2010 n=450/460 follow-up: 30 days	IV enoxaparin versus UFH	patients undergoing PCI for acute STEMI	Parallel groups open Austria, France, Germany, and US
Brieger n=346/234 follow-up:	enoxaparin versus unfractionated heparin	patients undergoing percutaneous coronary intervention for ST-segment elevation myocardial infarction (STEMI)	
CRUISE , 2003 n=129/132 follow-up: 2,7 +30 days	Enoxaparin 0.75 mg/kg bolus versus 65279;UFH 60 IU/kg bolus, then titrated to ACT >200	Urgent or elective PCI	Parallel groups open
Drozd , 2001 n=50/50 follow-up: 24hrs, 30 days	65279;Enoxaparin 1 mg/kg bolus versus UFH 100 IU/kg bolus	PCI for stable angina	
Dudek , 2000 n=200/200 follow-up: 3 days	Enoxaparin 1 mg/kg bolus versus UFH titrated to ACT >300	PCI	
Dudek b (enox alone) , 2000 n=NA follow-up:	Enoxaparin 1 mg/kg bolus versus UFH titrated to ACT >300	PTCA complex lesionsCI	
Galeote , 2001 n=50/49 follow-up:	Enoxaparin 0.75 mg/kg bolus versus UFH 70 U/kg bolus, then titrated to ACT >200	PTCA patients with stable/unstable angina or AMI	

continued...

Trial	Treatments	Patients	Trials design and methods
Rabah , 1999 n=30/30 follow-up:	Enoxaparin 1 mg/kg bolus versus 65279;UFH 10,000 IU bolus, then titrated to ACT >300	PCI for stable angina	Parallel groups open
STEEPLE , 2006 [NCT00077844] n=NA follow-up:	enoxaparin (0.5 or 0.75 mg per kilogram of body weight) versus unfractionated heparin (adjusted for activated clotting time)	elective percutaneous coronary intervention.	Parallel groups open
enoxaparin+abciximab vs UFH			
Dubek b (+abciximal) , 2001 n=NA	Enoxaparin 0.75 mg/kg bolus + abciximab versus UFH titrated to ACT >300	-	
reviparin vs UFH			
REDUCE , 1996 n=306/306 follow-up: 3 days	65279;Reviparin 7,000 IU anti-Xa versus UFH 10,000 IU bolus	PTCA with stable/unstable angina	Parallel groups double blind Europe and Canada
dalteparin vs UFH + anti Gp2b3a			
Natarajan (+ antiGp2b3a) , 2003 n=NA	Dalteparin 70 IU/kg bolus + GP IIb/IIIa inhibitorse/p versus 65279;UFH 70 IU/kg bolus +GPIIb/IIIa inhibitors	-	
enoxaparin vs unfractionated heparin			
STREAM *ongoing* [NCT00882635] n=NA follow-up:	Enoxaparin versus Unfractionated Heparin	St Elevation Myocardial Infarction patients undergoing primary percutaneous coronary intervention	

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7 P2Y12 receptor antagonist

Trial	Treatments	Patients	Trials design and methods
elinogrel vs clopidogrel			
INNOVATE PCI [NCT00751231] n=NA follow-up:	-	-	

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8 reversible ADP receptor antagonist

Trial	Treatments	Patients	Trials design and methods
cangrelor vs clopidogrel			
CHAMPION PHOENIX , 2013 [NCT01156571] n=5472/5470 follow-up: 48 hours	bolus and infusion of cangrelor followed by 600mg clopidogrel immediately post-infusion versus loading dose of 600 mg or 300 mg of clopidogrel	patients undergoing PCI for stable angina or for acute coronary syndromes, including ST-elevation MI	Parallel groups double-blind
cangrelor up front vs clopidogrel up front			
CHAMPION-PCI , 2009 [NCT00305162] n=4367/4355 follow-up: 48 h	cangrelor up front (cangrelor administered before percutaneous coronary intervention and followed by clopidogrel) versus clopidogrel up front (clopidogrel followed by placebo)	high risk patients requiring PCI	Parallel groups double blind 14 countries
cangrelor up front vs delayed clopidogrel			
CHAMPION-PLATFORM , 2009 [NCT00385138] n=2693/2669 follow-up: 48 h	cangrelor up front (cangrelor during PCI followed by 600 mg of clopidogrel) versus delayed clopidogrel (placebo during PCI followed by 600 mg of clopidogrel)	patients with acute coronary syndrome undergoing percutaneous coronary intervention	Parallel groups double blind 18 countries

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9 thienopyridine

Trial	Treatments	Patients	Trials design and methods
prasugrel vs clopidogrel			
TRITOM TIMI 38 (PCI subgroup) , 2009 n=1769/1765 follow-up:	prasugrel (60 mg loading, 10 mg maintenance) versus clopidogrel (300 mg loading, 75 mg maintenance)	subgroup of patients undergoing percutaneous coronary intervention for ST-elevation myocardial infarction	
JUMBO-TIMI 26 , 2005 n=650/254 follow-up: 30 days	Prasugrel 3 doses versus clopidogrel 300mg loading dose followed by 75 mg daily)	patients undergoing elective or urgent percutaneous coronary intervention	Parallel groups double blind
TRIGGER-PCI *ongoing* [NCT00910299] n=NA follow-up: 6 months	prasugrel one time 60-mg oral loading dose and 10-mg once daily oral maintenance dose up to 6 months versus clopidogrel 75-mg oral daily maintenance dose up to 6 months	patients With High Platelet Reactivity on Clopidogrel Following Elective Percutaneous Coronary Intervention With Implantation of Drug-Eluting Stent	Parallel groups double blind
Prasugrel and Bivalirudin vs Clopidogrel and Heparin			
BRAVE-4 *ongoing* [NCT00976092] n=NA follow-up:	Prasugrel + Bivalirudin versus Clopidogrel + Heparin	STEMI patients undergoing PPCI	

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TRIGGER-PCI, :

BRAVE-4, :

10 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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