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

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1 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			
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

continued...

Trial	Treatments	Patients	Trials design and methods
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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2 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, :

3 Low Molecular Weight Heparin

Trial	Treatments	Patients	Trials design and methods
dalteparin vs UFH			

continued...

Trial	Treatments	Patients	Trials design and methods
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	
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			

continued...

Trial	Treatments	Patients	Trials design and methods
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	-	

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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.

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