Clinical trials of bivalirudin

TrialResults-center www.trialresultscenter.org

1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
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

More details and results :

- antithrombotics for acute myocardial infarction in all type of patients at http://www.trialresultscenter.org/go-Q36

References

HERO, 1997:

White HD, Aylward PE, Frey MJ, Adgey AA, Nair R, Hillis WS, Shalev Y, Brown MA, French JK, Collins R, Maraganore J, Adelman B Randomized, double-blind comparison of hirulog versus heparin in patients receiving streptokinase and aspirin for acute myocardial infarction (HERO). Hirulog Early Reperfusion/Occlusion (HERO) Trial Investigators. Circulation 1997 Oct 7;96:2155-61 [9337184]

2 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
bivalirudin vs heparin + GP2b3a inhibitors			
ACUITY (biva alone vs hep+aGP2b3a) , 2006 [NCT00093158] n=4612/4603 follow-up: 30 days	bivalirudin alone versus unfractionated heparin or enoxaparin plus a glycoprotein IIb/IIIa inhibitor	in patients with moderate- or high-risk acute coronary syndromes who were undergoing an early invasive strategy.	Parallel groups double blind 17 countries worldwide

continued...

Trial	Treatments	Patients	Trials design and methods
ACUITY (sub groups PCI, bivalirudin alone) import , 2007 n=2619/2561 follow-up: 30 days	bivalirudin alone versus heparin (either unfractionated or enoxaparin) plus glycoprotein IIb/IIIa inhibitors	patients with moderate and high-risk acute coronary syndromes undergoing percutaneous coronary intervention after angiography (sub group).	Factorial plan open
bivalirudin + GP2b3a inhibitors vs heparin + GP2b3a inhibitors			
ACUITY (biva+aGP2b3a vs hep+aGP2b3a) , 2006 [NCT00093158] n=4604/4603 follow-up: 30 days	bivalirudin plus a glycoprotein IIb/IIIa inhibitor versus unfractionated heparin or enoxaparin plus a glycoprotein IIb/IIIa inhibitor	in patients with moderate- or high-risk acute coronary syndromes who were undergoing an early invasive strategy.	double blind 17 countries worldwide
ACUITY (sub groups PCI, bivalirudin +aGP2b3a) import , 2007 n=2609/2561 follow-up: 30 days	bivalirudin + versus heparin (either unfractionated or enoxaparin) plus glycoprotein IIb/IIIa inhibitors	patients with moderate and high-risk acute coronary syndromes undergoing percutaneous coronary intervention after angiography.	open
bivalirudin vs eptifibatide + heparin			
PROTECT-TIMI 30 , 2006 [NCT00250471] n=284/573 follow-up: hospital stay	bivalirudin alone versus eptifibatide plus either unfractionated heparin or enoxaparin	non ST elevation ACS patients undergoing PCI	Parallel groups open International
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
BAT (Bittl) , 1995 n=2059/2039 follow-up: 6 months	Bivalirudin 1.0 mg/kg bolus; 2.5 mg /kg/h for 4 h, then 0.2 mg /kg/h infusion for 24h versus UFH 175 IU/kg bolus; 15 IU mg /kg/h infusion	patients undergoing angioplasty for unstable or postinfarction angina	Parallel groups double blind North America and Europe

More details and results :

- antithrombotics for acute coronary syndrome in all type of patients at http://www.trialresultscenter.org/go-Q24
- antithrombotics for acute coronary syndrome in patients managed with an early invasive strategy at http://www.trialresultscenter.org/go-Q347

- antithrombotics for acute coronary syndrome in PCI sub group at http://www.trialresultscenter.org/go-Q348

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3 percutaneous coronary intervention

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

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Trial	Treatments	Patients	Trials design and methods
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
Prasugrel and Bivalirudin vs Clopidogrel and Heparin			
BRAVE-4 *ongoing* [NCT00976092] n=NA follow-up:	Prasugrel + Bivalirudin versus Clopidogrel + Heparin	STEMI patients undergoing PPCI	

More details and results :

- antithrombotics for percutaneous coronary intervention in all type of patients at http://www.trialresultscenter.org/go-Q63
- anticoagulant for percutaneous coronary intervention in all type of patients at http://www.trialresultscenter.org/go-Q388

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ongoing trial NCT00976092

Entry terms: Hirulog-1 Hirulog Angiomax