

# Clinical trials of Hirudin

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## 1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>Hirudin vs heparin</b>			
<b>HIT-4 , 1999</b> 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
<b>TIMI 9B , 1996</b> 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

More details and results :

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

## References

### HIT-4, 1999:

Neuhaus KL, Molhoek GP, Zeymer U, Tebbe U, Wegscheider K, Schroder R, Camez A, Laarman GJ, Grollier GM, Lok DJ, Kuckuck H, Lazarus P Recombinant hirudin (lepirudin) for the improvement of thrombolysis with streptokinase in patients with acute myocardial infarction: results of the HIT-4 trial. J Am Coll Cardiol 1999 Oct;34:966-73 [[10520777](#)]

### TIMI 9B, 1996:

Antman EM Hirudin in acute myocardial infarction. Thrombolysis and Thrombin Inhibition in Myocardial Infarction (TIMI) 9B trial. Circulation 1996 Sep 1;94:911-21 [[8790025](#)]

## 2 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
<b>Hirudin vs heparin</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>HIT-4 , 1999</b> 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
<b>OASIS , 1997</b> n=538/371 follow-up: 7 days	low-dose hirudin (0.2 mg/kg bolus+0.10 mg/kg/h infusion) or medium-dose hirudin (0.4 mg/kg bolus+0.15 mg/kg/h infusion) for 72h versus heparin 5000 IU bolus+1000 to 1200 U/h	patients with unstable angina or suspected acute MI without ST-segment elevation	Parallel groups open
<b>TIMI 9B , 1996</b> 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
<b>GUSTO IIB , 1996</b> n=12142 follow-up: 30days (1 year)	Hirudin 0.1 mg/kg bolus; 0.1 mg /kg/h infusion for 72h versus UFH 5000 IU bolus; 1000 IU/h infusion for 72H	patients with acute coronary syndromes	Parallel groups open
<b>OASIS pilot , 1997</b> n=909 follow-up: 6 months	Hirudin 0.20.4 mg/kg bolus; 0.100.15 mg /kg/h infusion for 72h versus UFH 5000 IU bolus; 10001200 IU/h infusion	patients with unstable angina or suspected acute MI without ST-segment elevation	Parallel groups open
<b>OASIS 2 , 1999</b> n=5083/5058 follow-up: 7 days (6 months)	Hirudin 0.4 mg/kg bolus; 0.15 mg /kg/h infusion for 72h versus UFH 5000 IU bolus; 15 IU /kg/h infusion	patients with unstable angina or suspected acute myocardial infarction without ST elevation	Parallel groups double blind
<b>HELVETICA (Serruys) , 1995</b> n=1141 follow-up: 6 months	Hirudin 40 mg intravenous bolus; 0.2 mg /kg/h infusion for 24 h, then 40 mg or placebo twice daily for 72h versus UFH 10 000 IU bolus; 15 IU /kg/h infusion for 24 h, then placebo twice daily	patients with unstable angina who were scheduled for angioplasty	Parallel groups double blind

More details and results :

- antithrombotics for acute coronary syndrome in all type of patients at <http://www.trialresultscenter.org/go-Q24>

## References

### **HIT-4, 1999:**

Neuhaus KL, Molhoek GP, Zeymer U, Tebbe U, Wegscheider K, Schroder R, Camez A, Laarman GJ, Grollier GM, Lok DJ, Kuckuck H, Lazarus P Recombinant hirudin (lepirudin) for the improvement of thrombolysis with streptokinase in patients with acute myocardial infarction: results of the HIT-4 trial. *J Am Coll Cardiol* 1999 Oct;34:966-73 [[10520777](#)]

### **OASIS, 1997:**

Comparison of the effects of two doses of recombinant hirudin compared with heparin in patients with acute myocardial ischemia without ST elevation: a pilot study. Organization to Assess Strategies for Ischemic Syndromes (OASIS) Investigators. *Circulation* 1997 Aug 5;96:769-77 [[9264481](#)]

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### **OASIS pilot, 1997:**

Effects of recombinant hirudin (lepirudin) compared with heparin on death, myocardial infarction, refractory angina, and revascularisation procedures in patients with acute myocardial ischaemia without ST elevation: a randomised trial. Organisation to Assess Strategies for Ischemic Syndromes (OASIS-2) Investigators. *Lancet* 1999 Feb 6;353:429-38 [[9989712](#)]

Comparison of the effects of two doses of recombinant hirudin compared with heparin in patients with acute myocardial ischemia without ST elevation: a pilot study. Organization to Assess Strategies for Ischemic Syndromes (OASIS) Investigators. *Circulation* 1997 Aug 5;96:769-77 [[9264481](#)]

### **OASIS 2, 1999:**

Effects of recombinant hirudin (lepirudin) compared with heparin on death, myocardial infarction, refractory angina, and revascularisation procedures in patients with acute myocardial ischaemia without ST elevation: a randomised trial. Organisation to Assess Strategies for Ischemic Syndromes (OASIS-2) Investigators. *Lancet* 1999;353:429-38 [[9989712](#)]

### **HELVETICA (Serruys), 1995:**

Serruys PW, Herrman JP, Simon R, Rutsch W, Bode C, Laarman GJ, van Dijk R, van den Bos AA, Umans VA, Fox KA A comparison of hirudin with heparin in the prevention of restenosis after coronary angioplasty. *Helvetica Investigators. N Engl J Med* 1995 Sep 21;333:757-63 [[7643882](#)]

Entry terms: hirudin