Clinical trials of fondaparinux

TrialResults-center www.trialresultscenter.org

1 acute myocardial infarction

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

More details and results :

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

References

MICHELANGELO OASIS-6, 2006:

Yusuf S, Mehta SR, Chrolavicius S, Afzal R, Pogue J, Granger CB, Budaj A, Peters RJ, Bassand JP, Wallentin L, Joyner C, Fox KA Effects of fondaparinux on mortality and reinfarction in patients with acute ST-segment elevation myocardial infarction: the OASIS-6 randomized trial. JAMA 2006;295:1519-30 [16537725] 10.1001/jama.295.13.joc60038

2 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
fondaparinux vs enoxaparin			
OASIS 5 , 2006 [NCT00139815] n=10057/10021 follow-up: 9 days (180 days)	fondaparinux 2.5 mg daily until hospital discharge or for up to eight days versus enoxaparin 1 mg per kilogram of body weight twice daily for two to eight days or until the patient was in clinically stable condition	patients with acute coronary syndromes	Parallel groups double blind 41 countires

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Trial	Treatments	Patients	Trials design and methods
PENTUA , 2004 n=908/230 follow-up: 9 days	Four doses fondaparinux (2.5, 4, 8, or 12 mg once daily) for three to seven days versus enoxaparin (1 mg/kg twice daily) for three to seven days	patients with ACS without persistent ST-segment elevation	

More details and results :

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

References

OASIS 5, 2006:

Yusuf S, Mehta SR, Chrolavicius S, Afzal R, Pogue J, Granger CB, Budaj A, Peters RJ, Bassand JP, Wallentin L, Joyner C, Fox KA Comparison of fondaparinux and enoxaparin in acute coronary syndromes. N Engl J Med 2006;354:1464-76 [16537663]

Jolly SS, Faxon DP, Fox KA, Afzal R, Boden WE, Widimsky P, Steg PG, Valentin V, Budaj A, Granger CB, Joyner CD, Chrolavicius S, Yusuf S, Mehta SR Efficacy and safety of fondaparinux versus enoxaparin in patients with acute coronary syndromes treated with glycoprotein IIb/IIIa inhibitors or thienopyridines: results from the OASIS 5 (Fifth Organization to Assess Strategies in Ischemic Syndromes) trial. J Am Coll Cardiol 2009;54:468-76 [19628124]

PENTUA, 2004:

Simoons ML, Bobbink IW, Boland J, Gardien M, Klootwijk P, Lensing AW, Ruzyllo W, Umans VA, Vahanian A, Van De Werf F, Zeymer U A dose-finding study of fondaparinux in patients with non-ST-segment elevation acute coronary syndromes: the Pentasaccharide in Unstable Angina (PENTUA) Study. J Am Coll Cardiol 2004;43:2183-90 [15193678]

3 DVT prophylaxis

Trial	Treatments	Patients	Trials design and methods
fondaparinux vs placebo			
DRI4757 n=345/87 follow-up: 14 days	fondaparinux subcutaneously at 0.75, 1.5, 2.5, and 3.0 mg for at least 10 calendar days, (with a maximum of 14 days) versus placebo	Japanese patients undergoing elective total knee replacement surgery	Parallel groups double blind Japan
ARTEMIS (Cohen) , 2006 n=425/414 follow-up: 6-15 days	Fondaparinux 2.5 mg once daily for 614 days versus placebo	High-risk medical patients	Parallel groups double blind 8 countries

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Trial	Treatments	Patients	Trials design and methods
fondaparinux vs placebo (on top intermittent pneumatic comp.)			
APOLLO (Turpie) , 2007 n=650/659 follow-up: 10 days	fondaparinux 2.5 mg s.c. for 5-9 days, starting 6-8 h postoperatively + intermittent pneumatic compression versus placebo s.c. for 5-9 days, starting 6-8 h postoperatively + intermittent pneumatic compression	Patients aged at least 40 years undergoing abdominal surgery	Parallel groups double blind US
fondaparinux vs control			
NCT00333021 *ongoing* [NCT00333021] n=NA follow-up:	-	Abdominal Surgery	Parallel groups open japan
NCT00320398 *ongoing* [NCT00320398] n=NA follow-up:	-	patients undergoing either an elective primary total hip replacement (THR) surgery or a revision of a THR	double-blind Japan
fondaparinux vs no treatment			
PROTECT (fundaparinux) *ongoing* [NCT00881088] n=NA follow-up:	fondaparinux 2,5 mg daily group during immobilization versus no treatment	Patients with a nonsurgical fracture of the lower extremity immobilised in a below-knee plaster cast	Parallel groups single blind
fondaparinux vs enoxaparin			
BRiEF [NCT00521885] n=NA follow-up:	fondaparinux 2.5mg qd versus enoxaparin 40mg qd	acute medically ill, non-surgical patients	Parallel groups Germany
L8541 n=119/118 follow-up: 9 days (49d)	fondaparinux 2.5mg subcutaneous once-daily for 7+/-2 days versus enoxaparin 40mg s.c. once-daily	chinese patients undergoing major orthopaedic surgery of the lower limbs	Parallel groups single-blind China
L8635 n=28/23 follow-up: 10 days	Fondaparinux 2.5mg once daily subcutaneously for 7 days versus enoxaparin 40mg once daily SC for 7 days	Taiwanese patients undergoing elective knee replacement	Parallel groups open, blind assessment Taiwan

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Trial	Treatments	Patients	Trials design and methods
PENTAMAKS (Bauer) , 2001 n=517/517 follow-up: 11 days	fondaparinux 2.5-mg once-daily subcutaneous, starting 6 hours after surgery versus enoxaparin 30mg twice daily (North america recommendation)	elective major knee surgery	Parallel groups double blind North america
PENTHIFRA (Eriksson) , 2001 n=831/840 follow-up: 11 days	fondaparinux 2.5-mg once-daily subcutaneous, starting 6 hours after surgery versus enoxaprin 40mg once daily	hip fracture surgery	Parallel groups double blind 21 countries
EPHESUS (Lassen) , 2002 n=1155/1154 follow-up: 11 days (6 weeks)	fondaparinux 2.5-mg once-daily subcutaneous, starting 6 hours after surgery versus enoxaprin 40mg once daily	elective hip replacement surgery	Parallel groups double blind 16 European countries
PENTATHLON (Turpie) , 2002 n=1138/1137 follow-up: 11 days	fondaparinux 2.5-mg once-daily subcutaneous, starting 6 hours after surgery versus enoxaparin 30mg twice daily (North america recommendation)	elective hip replacement surgery	Parallel groups double blind USA, Canada, Australia
PEGASUS , 2005 n=1465/1462 follow-up: 10 days (30 days)	once-daily subcutaneous injections of fondaparinux 25 mg started 6 h after surgery for 59 days versus once-daily subcutaneous injections of dalteparin 5000 units for 59 days (2500 units each, given 2 h before surgery and 12 h after the preoperative administration)	patients undergoing major abdominal surgery	Parallel groups double blind 22 countries
Turpie , 2001 n=673/260 follow-up: >15 days	pentasaccharide Org31540/SR90107A subcutaneous once daily at doses 0.75 mg, 1.5 mg, 3.0 mg, 6.0 mg, and 8.0 mg versus enoxaparin 30mg once daily subcutaneous	patients undergoing total hip replacement	Parallel groups double blind US, Canada, Autralia
fondaparinux vs nadroparin			

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Trial	Treatments	Patients	Trials design and methods
FONDACAST *ongoing* [NCT00843492] n=NA follow-up: 5 weeks	subcutaneously, once daily, fondaparinux 2.5 mg for at least 21 Days, up to complete mobilization, with a maximal duration of treatment of 45 days versus daily nadroparin 2850 anti-Xa IU (0.3 mL) for at least 21 Days, up to complete mobilization	patients requiring rigid or semi-rigid immobilization for at least 21 days and up to 45 days because of isolated non-surgical below-knee injury	Parallel groups open Europe

More details and results :

- antithrombotics for DVT prophylaxis in orthopedic surgery at http://www.trialresultscenter.org/go-Q37
- antithrombotics for DVT prophylaxis in elective major knee surgery at http://www.trialresultscenter.org/go-Q38
- antithrombotics for DVT prophylaxis in elective hip replacement at http://www.trialresultscenter.org/go-Q39
- antithrombotics for DVT prophylaxis in hip Fracture at http://www.trialresultscenter.org/go-Q40
- antithrombotics for DVT prophylaxis in medical patients at http://www.trialresultscenter.org/go-Q87
- antithrombotics for DVT prophylaxis in abdominal surgery at http://www.trialresultscenter.org/go-Q96
- pentasaccharide for DVT prophylaxis in orthopedic surgery at http://www.trialresultscenter.org/go-Q188
- pentasaccharide for DVT prophylaxis in abdominal surgery at http://www.trialresultscenter.org/go-Q213
- pentasaccharide for DVT prophylaxis in medical patients at http://www.trialresultscenter.org/go-Q380
- pentasaccharide for DVT prophylaxis in all type of patients at http://www.trialresultscenter.org/go-Q396
- antithrombotics for DVT prophylaxis in patients with immobilization of the lower extremities at http://www.trialresultscenter.org/go-Q405

References

DRI4757, 0:

ARTEMIS (Cohen), 2006:

Cohen AT, Davidson BL, Gallus AS, Lassen MR, Prins MH, Tomkowski W, Turpie AG, Egberts JF, Lensing AW Efficacy and safety of fondaparinux for the prevention of venous thromboembolism in older acute medical patients: randomised placebo controlled trial. BMJ 2006;332:325-9 [16439370]

APOLLO (Turpie), 2007:

Turpie AG, Bauer KA, Caprini JA, Comp PC, Gent M, Muntz JE Fondaparinux combined with intermittent pneumatic compression vs. intermittent pneumatic compression alone for prevention of venous thromboembolism after abdominal surgery: a randomized, double-blind comparison. J Thromb Haemost 2007;5:1854-61 [17723125]

NCT00333021, :

ongoing trial NCT00333021

NCT00320398, 0:

ongoing trial NCT00320398

PROTECT (fundaparinux), :

ongoing trial NCT00881088

BRiEF, :

L8541, 0:

L8635, 0:

PENTAMAKS (Bauer), 2001:

Bauer KA, Eriksson BI, Lassen MR, Turpie AG Fondaparinux compared with enoxaparin for the prevention of venous thromboembolism after elective major knee surgery. N Engl J Med 2001 Nov 1;345:1305-10 [11794149]

PENTHIFRA (Eriksson), 2001:

Eriksson BI, Bauer KA, Lassen MR, Turpie AG Fondaparinux compared with enoxaparin for the prevention of venous thromboembolism after hip-fracture surgery. N Engl J Med 2001 Nov 1;345:1298-304 [11794148]

EPHESUS (Lassen), 2002:

Lassen MR, Bauer KA, Eriksson BI, Turpie AG Postoperative fondaparinux versus preoperative enoxaparin for prevention of venous thromboembolism in elective hip-replacement surgery: a randomised double-blind comparison. Lancet 2002 May 18;359:1715-20 [12049858]

PENTATHLON (Turpie), 2002:

Turpie AG, Bauer KA, Eriksson BI, Lassen MR Postoperative fondaparinux versus postoperative enoxaparin for prevention of venous thromboembolism after elective hip-replacement surgery: a randomised double-blind trial. Lancet 2002 May 18;359:1721-6 [12049860]

PEGASUS, 2005:

Agnelli G, Bergqvist D, Cohen AT, Gallus AS, Gent M Randomized clinical trial of postoperative fondaparinux versus perioperative dalteparin for prevention of venous thromboembolism in high-risk abdominal surgery. Br J Surg 2005;92:1212-20 [16175516]

Turpie, 2001:

Turpie AG, Gallus AS, Hoek JA A synthetic pentasaccharide for the prevention of deep-vein thrombosis after total hip replacement. N Engl J Med 2001;344:619-25 [11228275]

FONDACAST, :

ongoing trial NCT00843492

4 venous thrombosis

Trial	Treatments	Patients	Trials design and methods
fondaparinux vs enoxaparin			
MATISSE , 2004 n=1098/1107 follow-up: 3 months	fondaparinux 7.5 mg subcutaneously once daily for at least 5 days and until vitamin K antagonists induced an INR greater than 2.0. versus enoxaparin, 1 mg/kg of body weight, subcutaneously twice daily for at least 5 days and until vitamin K antagonists induced an INR greater than 2.0.	patients with acute symptomatic deep venous thrombosis	Parallel groups double blind international
fondaparinux vs heparin			
MATISSE PE , 2003 n=1103/1110 follow-up: 3 mo	fondaparinux subcutaneously once daily versus continuous intravenous infusion of unfractionated heparin	patients with acute symptomatic pulmonary embolism	Parallel groups open

More details and results :

- antithrombotics for venous thrombosis in all type of patients at http://www.trialresultscenter.org/go-Q101

References

MATISSE, 2004:

Bller HR, Davidson BL, Decousus H, Gallus A, Gent M, Piovella F, Prins MH, Raskob G, Segers AE, Cariou R, Leeuwenkamp O, Lensing AW Fondaparinux or enoxaparin for the initial treatment of symptomatic deep venous thrombosis: a randomized trial. Ann Intern Med 2004;140:867-73 [15172900]

MATISSE PE, 2003:

Bller HR, Davidson BL, Decousus H, Gallus A, Gent M, Piovella F, Prins MH, Raskob G, van den Berg-Segers AE, Cariou R, Leeuwenkamp O, Lensing AW Subcutaneous fondaparinux versus intravenous unfractionated heparin in the initial treatment of pulmonary embolism. N Engl J Med 2003 Oct 30;349:1695-702 [14585937]

5 percutaneous coronary intervention

Trial	Treatments	Patients	Trials design and methods
fondaparinux vs unfractionated heparin or bivalirudin			

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Trial	Treatments	Patients	Trials design and methods
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

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

References

SWITCH III, :
ongoing trial NCT00464087

6 pulmonary embolism

Trial	Treatments	Patients	Trials design and methods
fondaparinux vs heparin			
MATISSE PE , 2003 n=1103/1110 follow-up: 3 mo	fondaparinux subcutaneously once daily versus continuous intravenous infusion of unfractionated heparin	patients with acute symptomatic pulmonary embolism	Parallel groups open

More details and results :

- antithrombotics for pulmonary embolism in all type of patients at http://www.trialresultscenter.org/go-Q102

References

MATISSE PE, 2003:
Bller HR, Davidson BL, Decousus H, Gallus A, Gent M, Piovella F, Prins MH, Raskob G, van den Berg-Segers AE, Cariou R, Leeuwenkamp O, Lensing AW Subcutaneous fondaparinux versus intravenous unfractionated heparin in the initial treatment of pulmonary embolism. N Engl J Med 2003 Oct 30;349:1695-702 [14585937]

7 superficial thrombophlebitis

Trial	Treatments	Patients	Trials design and methods
fondaparinux vs placebo			
CALISTO , 2010 [NCT00443053] n=1502/1500 follow-up: 45 days (77d)	fondaparinux 2.5mg up to 45 days versus placebo	patients with acute symptomatic isolated superficial thrombophlebitis of the lower limbs	Parallel groups double blind 17 countries

More details and results :

- antithrombotics for superficial thrombophlebitis in superficial thrombophlebitis of the leg at http://www.trialresultscenter.org/go-Q218

References

CALISTO, 2010:

Bauersachs R., Dcousus H., Prandoni P., Leizorovicz A., For the CALISTO Investigators Fondaparinux 2.5 mg for the treatment of superficial vein thrombosis (SVT): the randomized double-blind placebo-controlled CALISTO trial in 3002 patients

Decousus H, Prandoni P, Mismetti P, Bauersachs RM, Boda Z, Brenner B, Laporte S, Matyas L, Middeldorp S, Sokurenko G, Leizorovicz A Fondaparinux for the treatment of superficial-vein thrombosis in the legs. N Engl J Med 2010 Sep 23;363:1222-32 [20860504] 10.1056/NEJMoa0912072

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