Clinical trials of idraparinux

TrialResults-center www.trialresultscenter.org

1 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
idraparinux vs warfarin standard dose			
AMADEUS , 2008 [NCT00070655] n=2283/2293 follow-up: 10.7 months	subcutaneous idraparinux 25 mg weekly versus adjusted-dose vitamin K antagonists (target of an international normalised ratio of 23)	patients with atrial fi brillation at risk for thromboembolism	Parallel groups open
idraparinux BOREALIS-AF *ongoing* [NCT00580216] n=NA follow-up:	idraparinuxonce-weekly subcutaneous injection versus warfarin oral INR adjusted-dose	-	Parallel groups double blind

More details and results :

- antithrombotics for atrial fibrillation in primary prevention of thromboembolic events at http://www.trialresultscenter.org/go-Q57
- direct oral anticoagulant (DAO) for atrial fibrillation in all type of patients at http://www.trialresultscenter.org/go-Q391

References

AMADEUS, 2008:

Bousser MG, Bouthier J, Bller HR, Cohen AT, Crijns H, Davidson BL, Halperin J, Hankey G, Levy S, Pengo V, Prandoni P, Prins MH, Tomkowski W, Thorp-Pedersen C, Wyse DG Comparison of idraparinux with vitamin K antagonists for prevention of thromboembolism in patients with atrial fibrillation: a randomised, open-label, non-inferiority trial. Lancet 2008;371:315-21 [18294998]

idraparinux BOREALIS-AF, 0:

ongoing trial NCT00580216

2 venous thrombosis

Trial	Treatments	Patients	Trials design and methods
idraparinux vs discontinuation			
VanGogh extension , 2007 [NCT00071279] n=594/621 follow-up: 6 months	once-weekly injections of 2.5 mg of idraparinux for 6 months versus placebo	patients who had completed 6 months of prophylaxis with idraparinux or a vitamin K antagonist and in whom extended anticoagulation was warranted	Parallel groups
idraparinux vs placebo			
Van Gogh , 2007 [NCT00071279] n=594/621 follow-up:	once-weekly injections of 2.5 mg of idraparinux for 6 months without monitoring versus placebo	patients who had completed 6 months of prophylaxis with idraparinux or a vitamin K antagonist and in whom extended anticoagulation was warranted	Parallel groups double-blind
idraparinux vs standard treatment			
Van Gogh (subgroup) , 2011 n=220/201 follow-up: 6 months	once-weekly subcutaneous injection of idraparinux (2.5 mg) for 6 months versus standard treatment for three months (8%) or six months (92%)	non-active and active cancer patients with deep venous thrombosis and without pulmonary embolism, included in the Van Gogh DVT clinical trial	Parallel groups
idraparinux (without heparin) vs heparin/VKA			
VanGogh DVT , 2007 [NCT00067093] n=1452/1452 follow-up: 3 mo (6 mo)	subcutaneous idraparinux (2.5 mg once weekly) versus heparin followed by an adjusted-dose vitamin K antagonist	patients with deep-vein thrombosis	Parallel groups open
VanGogh PE , 2007 [NCT00062803] n=1095/1120 follow-up: 3 mo (6 mo)	subcutaneous idraparinux (2.5 mg once weekly) versus heparin followed by an adjusted-dose vitamin K antagonist	patients with 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
- antithrombotics for venous thrombosis in patients with cancer at http://www.trialresultscenter.org/go-Q103
- antithrombotics for venous thrombosis in secondary prevention of VTE at http://www.trialresultscenter.org/go-Q149
- direct oral anticoagulant (DAO) for venous thrombosis in all types of patients at http://www.trialresultscenter.org/go-Q505
- antithrombotics for venous thrombosis in secondary prevention - 2 at http://www.trialresultscenter.org/go-Q682

- direct oral anticoagulant (DAO) for venous thrombosis in patients with cancer at http://www.trialresultscenter.org/go-Q737

References

VanGogh extension, 2007:

Buller HR, Cohen AT, Davidson B, Decousus H, Gallus AS, Gent M, Pillion G, Piovella F, Prins MH, Raskob GE N Engl J Med 2007 Sep 13;357:1105-12 [17855671] 10.1056/NEJMoa067703

Van Gogh, 2007:

Buller HR, Cohen AT, Davidson B, Decousus H, Gallus AS, Gent M, Pillion G, Piovella F, Prins MH, Raskob GE Extended prophylaxis of venous thromboembolism with idraparinux. N Engl J Med 2007;357:1105-12 [17855671] 10.1056/NEJMoa067703

Van Gogh (subgroup), 2011:

van Doormaal FF, Cohen AT, Davidson BL, Decousus H, Gallus AS, Gent M, Piovella F, Prins MH, Raskob GE, Bller HR Idraparinux versus standard therapy in the treatment of deep venous thrombosis in cancer patients: a subgroup analysis of the Van Gogh DVT trial. Thromb Haemost 2010;104:86-91 [20508907] 10.1160/TH09-12-0870

VanGogh DVT, 2007:

Buller HR, Cohen AT, Davidson B, Decousus H, Gallus AS, Gent M, Pillion G, Piovella F, Prins MH, Raskob GE N Engl J Med 2007 Sep 13;357:1094-104 [17855670]

VanGogh PE, 2007:

Buller HR, Cohen AT, Davidson B, Decousus H, Gallus AS, Gent M, Pillion G, Piovella F, Prins MH, Raskob GE N Engl J Med 2007 Sep 13;357:1094-104 [17855670]

3 pulmonary embolism

Trial	Treatments	Patients	Trials design and methods
idraparinux (without heparin) vs heparin/VKA			
VanGogh PE , 2007 [NCT00062803] n=1095/1120 follow-up: 3 mo (6 mo)	subcutaneous idraparinux (2.5 mg once weekly) versus heparin followed by an adjusted-dose vitamin K antagonist	patients with 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

VanGogh PE, 2007:

Buller HR, Cohen AT, Davidson B, Decousus H, Gallus AS, Gent M, Pillion G, Piovella F, Prins MH, Raskob GE N Engl J Med 2007 Sep 13;357:1094-104 [17855670]

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