Clinical trials of vasodilators therapy for peripheral vascular diseases in all type of patients

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1 sympathectomie avec chirurgie

Trial	Treatments	Patients	Trials design and methods
sympathectomie vs contrle			
Barnes RW , 1977 n=25/26 follow-up: 3 ans	sympathectomie bilatrale L2-L4 versus absence de sympathectomie	AOMI stade II (80%) et III (20%)	Parallel groups Ouvert
Satiani B , 1982 n=29/38 follow-up: 11 mois	sympathectomie bilatrale L2-L4 versus absence de sympathectomie	AOMI stade non prcis	Parallel groups Ouvert

References

Barnes RW, 1977:

Value of concomitant sympathectomy in aortoiliac reconstruction. Results of a prospective, randomized study. Barnes RW, Baker WH, Shanik G, Maixner W, Hayes AC, Lin R, Clarke W Arch Surg 1977 Nov;112:1325-30 [921531]

Satiani B, 1982:

Prospective randomized study of concomitant lumbar sympathectomy with aortoiliac reconstruction. Satiani B, Liapis CD, Hayes JP, Kimmins S, Evans WE Am J Surg 1982 Jun;143:755-60 [7091512]

2 Vasodilator Agents

Trial	Treatments	Patients	Trials design and methods
vs			
Cornu C *ongoing* n=NA	-	259 patients avec AOMI stade II	
Farquhar JW *ongoing* n=NA	-	100 patients avec AOMI stades II ou III	
Vowden P *ongoing* n=NA	-	320 patients avec AOMI stade II	
naftidrofuryl IV vs control			

continued...

Trial	Treatments	Patients	Trials design and methods
Meehan , 1982 n=24/16 follow-up: 7 days	Naftidrofuryl (Nafronyl): par voie IV (200 mg*2/ jour pendant 2 heures dans 500 ml de srum sal isotonique) et par voie orale (200mg*3/ jour)+ repos au lit + rchauffement pendant 7 jours versus Repos au lit + rchauffement	AOMI stade III	Parallel groups Simple aveugle
buflomedil vs placebo			
Diamantopoulos , 2001 n=21/19 follow-up: 6 mois	Buflomedil 600 mg/ d versus placebo	Stade de la maladie: II de 3.4 ans en moyenne.	Parallel groups Double aveugle
LIMB , 2008 n=1043/1035 follow-up: 33 months	buflomedil 150-300 mg twice daily adjusted to creatinine clearance versus placebo	Patients >40 years with documented peripheral arterial obstructive disease, intermittent claudication, and an ankle-brachial index between 0.30 and 0.80	Parallel groups double blind 4 countries
cilostazol vs placebo			
Elam , 1998 n=NA follow-up:	cilostazol 100 mg twice daily versus placebo	-	Parallel groups double blind US
Otsuka 21-95-201 n=NA follow-up: 12 weeks	-	-	Parallel groups double blind US
Dawson , 1998 n=54/27 follow-up: 3 mois	Cilostazol 200 mg/d versus placebo	Stade de la maladie: II, avec dure des symptomes (annes) de : 6.25+/-0.82	Parallel groups Double aveugle
Beebe , 1999 n=346/170 follow-up: 6 mois	Cilostazol 100 ou 200 mg / j (2 groupes) versus placebo	AOMI stade II	Parallel groups Double aveugle
Dawson (cilostazol) , 2000 n=227/239 follow-up: 6 mois	Cilostazol 200 mg/d versus placebo	Stade de la maladie: II en situation chronique.	Parallel groups Double aveugle
Money , 1998 n=119/120 follow-up: 4 mois	Cilostazol 200 mg/d versus placebo	Stade de la maladie: II	Parallel groups Double aveugle
Strandness , 2002 n=265/129 follow-up: 6 mois	cilostazol 50 or 100 mg twice daily versus placebo	AOMI stade II.	Parallel groups Double aveugle
ginko biloba vs placebo			
Bauer , 1984 n=44/35 follow-up: 6 mois	ginko biloba 40 mg three times daily versus placebo	AOMI stade IIb	Parallel groups Double aveugle

continued...

Trial	Treatments	Patients	Trials design and methods
Peters , 1998 n=53/58 follow-up: 6 mois	ginko biloba EGb 761 three times daily versus placebo	AOMI stade IIb	Parallel groups Double aveugle
Naftidrofuryl vs placebo			
Clyne , 1980 n=63/65 follow-up: 6 mois	Naftidrofuryl 100 mg/d versus placebo	AOMI stade II	Parallel groups Double aveugle
NCIS , 2001 n=89/92 follow-up: 12 mois	naftidrofuryl 200 mg three times daily versus placebo	Stade de la maladie: II pendant 5.25 ans en moyenne	Parallel groups Double aveugle
NIQOL belgium , 2001 n=108/112 follow-up: 6 mois	Naftidrofuryl 200mg three times daily versus placebo	Stade de la maladie :II pendant 4.1 ans en moyenne	Parallel groups Double aveugle
NIQOL germany , 1999 n=142/127 follow-up: 6 mois	Naftidrofuryl 600 mg/d versus placebo	Stade de la maladie: II, dure (annes): 2.41+/-2.67 en moyenne.	Parallel groups Double aveugle
naftidrofuryl IV vs placebo			
Testart , 1994 n=20/17 follow-up: 8 jours	2 daily infusions of 400 mg of naftidrofuryl for 8 days versus placebo	AOMI stade III ou IV	Parallel groups Double aveugle
D'Hooge D , 2001 n=116/119 follow-up: 6 mois	- effet de naftidrofuryl sur la qualit de vie de patients souffrant de claudication intermittente stable : 3x200mg pdt 6 mois versus - placebo pdt 6 mois	- 235 patients - ge moyen 66,5 ans - 66,4% d'hommes	Parallel groups Double aveugle
pentoxifylline vs placebo			
APIC , 1989 n=37/37 follow-up: 12 mois	Pentoxifylline 800 mg/d versus placebo	Stade de la maladie : II, avec dure des symptmes de 10 mois en moyenne.	Factorial plan Double aveugle
Belcaro , 2002 n=30/30 follow-up: 6 mois	Pentoxifylline 1600 mg/d versus placebo	Stade de la maladie: II avec dure de la claudication de: 3+/- 2 mois en moyenne.	Parallel groups Double aveugle
Dawson (pentoxifylline) , 2000 n=232/239 follow-up: 6 mois	Pentoxifylline 1200 mg/d versus placebo	Stade de la maladie: II en situation chronique.	Parallel groups Double aveugle
Donaldson , 1984 n=40/40 follow-up: 2 mois	Oxpentifylline 600 mg/d versus placebo	AOMI stade II	Parallel groups Double aveugle
Porter , 1982 n=67/61 follow-up: 6 mois	Pentoxifylline between 600 mg/d and 1200 mg/d versus placebo	Stade de l'artriopathie: II, avec dure des symptomes de 2.9 ans en moyenne.	Parallel groups Double aveugle
naftidrofuryl IV vs prostacyclin			

continued...

Trial	Treatments	Patients	Trials design and methods
Negus , 1987 n=15/14 follow-up: 24 h	Naftidrofuryl 0.02 mg/kg/min, intra-arterial, 3 days versus intra-arterial prostacyclin 8 ng/kg/min, 3 days	Stade de la maladie: III: 55.2% ; IV: 44.8% Dure de la douleur (semaines): groupe contrle: 30 +/-54.2 groupe ttt: 19.7 +/- 44.6	Parallel groups Double aveugle

References

Cornu C, 0:

Patients with intermittent claudication : EGB761 Ginkgo Bilboa extracts (TANAKAN) versus Placebo

Farquhar JW, 0:

Extract of Ginkgo Biloba (EGB 761) and Vascular Function

Vowden P, 0:

Double-blind, randomised, placebo controlled study of the efficacy and safety of BMS-207940, a selective endothelin A receptor antagonist in subjects with intermittent claudication.

Meehan, 1982:

The usefulness of naftidrofuryl in severe peripheral ischaemia–a symptomatic assessment using linear analogue scales. Meehan SE, Preece PE, Walker WF Angiology 1982 Oct;33:625-34 [6751162]

Diamantopoulos, 2001:

Diamantopoulos EJ, Grigoriadou M, Ifanti G, Raptis Sa. Clinical and hemorheological effects of Buflomedil in diabetic subjects with intermittent claudication . International Angiology 2001; 20 (4):337-44.

LIMB, 2008:

Leizorovicz A, Becker F Oral buflomedil in the prevention of cardiovascular events in patients with peripheral arterial obstructive disease: a randomized, placebo-controlled, 4-year study. Circulation 2008 Feb 12;117:816-22 [18212283]

Elam, 1998:

Elam MB, Heckman J, Crouse JR, Hunninghake DB, Herd JA, Davidson M, Gordon IL, Bortey EB, Forbes WP Effect of the novel antiplatelet agent cilostazol on plasma lipoproteins in patients with intermittent claudication. Arterioscler Thromb Vasc Biol 1998;18:1942-7 [9848888]

Otsuka 21-95-201, :

Dawson, 1998:

Cilostazol has beneficial effects in treatment of intermittent claudication: results from a multicenter, randomized, prospective, double-blind trial. Dawson DL, Cutler BS, Meissner MH, Strandness DE Jr Circulation 1998 Aug 18;98:678-86 [9715861]

Beebe, 1999:

A new pharmacological treatment for intermittent claudication: results of a randomized, multicenter trial. Beebe HG, Dawson DL, Cutler BS, Herd JA, Strandness DE Jr, Bortey EB, Forbes WP Arch Intern Med 1999 Sep 27;159:2041-50 [10510990]

Dawson (cilostazol), 2000:

Dawson DL, Cutler BS, Hiatt WR, Hobson RW 2nd, Martin JD, Bortey EB, Forbes WP, Strandness DE Jr. A comparison of cilostazol and pentoxifylline for treating intermittent claudication. Am J Med 2000 Nov;109:523-30.

Money, 1998:

Effect of cilostazol on walking distances in patients with intermittent claudication caused by peripheral vascular disease. Money SR, Herd JA, Isaacsohn JL, Davidson M, Cutler B, Heckman J, Forbes WP J Vasc Surg 1998 Feb;27:267-74; discussion 274-5 [9510281]

Strandness, 2002:

Strandness DE Jr, Dalman RL, Panian S, Rendell MS, Comp PC, Zhang P, Forbes WP. Effect of cilostazol in patients with intermittent claudication: a randomized, double-blind, placebo-controlled study. Vasc Endovascular Surg 2002 Mar-Apr;36:83-91.

Bauer, 1984:

Bauer U. 6-Month double-blind randomised clinical trial of Ginkgo biloba extract versus placebo in two parallel groups in patients suffering from peripheral arterial insufficiency. Arzneimittelforschung 1984;34:716-20.

Peters, 1998:

Peters H, Kieser M, Holscher U. Demonstration of the efficacy of ginkgo biloba special extract EGb 761 on intermittent claudication–a placebo-controlled, double-blind multicenter trial. Vasa 1998 May;27:106-10.

Clyne, 1980:

Clyne CAC et al A controlled trial of naftidrofuryl in the treatment of intermittent claudication Br J Surg 1980 ; 67 : 347-8

NCIS, 2001:

A new study demonstrates the efficacy of naftidrofuryl in the treatment of intermittent claudication. Findings of the Naftidrofuryl Clinical Ischemia Study (NCIS). Kieffer E, Bahnini A, Mouren X, Gamand S Int Angiol 2001 Mar;20:58-65 [11342997]

NIQOL belgium, 2001:

D'Hooge D, Lehert P, Clement DL. Naftidrofuryl in quality of life (NIQOL). A Belgian study. International angiology 2001; 20(1): 58-65.

NIQOL germany, 1999:

Naftidrofuryl can enhance the quality of life in patients with intermittent claudication. Spengel F, Brown TM, Poth J, Lehert P Vasa 1999 Aug;28:207-12 [10483329]

Testart, 1994:

[Evaluation of the analgesic effect of naftidrofuryl in permanent ischemia in patients with arterial diseases. Double-blind versus placebo study] Testart J, Guidicelli H, Glanddier G, Mosnier M Ann Cardiol Angeiol (Paris) 1994 Nov;43:542-7 [7864561]

D'Hooge D, 2001:

D. D'Hooge; P.Lehert, D.L.Clement Naftidrofuryl in quality of life (NIQOL) A Belgian study. Int Angiol 2001;20:288-94

APIC, 1989:

Acenocoumarol and pentoxifylline in intermittent claudication. A controlled clinical study. The APIC Study Group. Dettori AG, Pini M, Moratti A, Paolicelli M, Basevi P, Quintavalla R, Manotti C, Di Lecce C Angiology 1989 Apr;40:237-48 [2650578]

Belcaro, 2002:

Intermittent claudication in diabetics: treatment with exercise and pentoxifylline–a 6-month, controlled, randomized trial. Belcaro G, Nicolaides AN, Griffin M, De Sanctis MT, Cesarone MR, Incandela L, Ippolito E, Pomante P, Geroulakos G, Ramaswami G Angiology 2002 Jan-Feb;53 Suppl 1:S39-43 [11865835]

Dawson (pentoxifylline), 2000:

A comparison of cilostazol and pentoxifylline for treating intermittent claudication. Dawson DL, Cutler BS, Hiatt WR, Hobson RW 2nd, Martin JD, Bortey EB, Forbes WP, Strandness DE Jr Am J Med 2000 Nov;109:523-30 [11063952]

Donaldson, 1984:

Does oxpentifylline ('Trental') have a place in the treatment of intermittent claudication? Donaldson DR, Hall TJ, Kester RC, Ramsden CW, Wiggins PA Curr Med Res Opin 1984;9:35-40 [6373157]

Porter, 1982:

Pentoxifylline efficacy in the treatment of intermittent claudication: multicenter controlled double-blind trial with objective assessment of chronic occlusive arterial disease patients. Porter JM, Cutler BS, Lee BY, Reich T, Reichle FA, Scogin JT, Strandness DE Am Heart J 1982 Jul;104:66-72 [7046409]

Negus, 1987:

Intra-arterial prostacyclin compared to Praxilene in the management of severe lower limb ischaemia: a double blind trial. Negus D, Irving JD, Friedgood A J Cardiovasc Surg (Torino) 1987 Mar-Apr;28:196-9 [2435738]

3 About TrialResults-center.org

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