Clinical trials of cholesterol lowering intervention for peripheral vascular diseases in all type of patients

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1 colestipol-niacin

Trial	Treatments	Patients	Trials design and methods
colestipol-niacin vs placebo			
CLAS , 1987 n=94/94 follow-up: 2 ans	Colestipol + Niacin 30 g / j 3-12 g / j (titr sur chaque patient sur la base de la baisse de cholestrol sanguin) versus placebo: methyl cellulose	Patients coronariens avec antcdent de revascularisation chirurgicale coronarienne.	Parallel groups Non dterminable

References

CLAS, 1987:

Blankenhorn DH, Brooks SH. Angiographic trials of lipid-lowering therapy. Arteriosclerosis 1981; 1: 242-249.

The Cholesterol Lowering Atherosclerosis Study (CLAS): design, methods, and baseline results. Blankenhorn DH, Johnson RL, Nessim SA, Azen SP, Sanmarco ME, Selzer RH Control Clin Trials 1987 Dec;8:356-87 [3327654]

Beneficial effects of combined colestipol-niacin therapy on coronary atherosclerosis and coronary venous bypass grafts. Blankenhorn DH, Nessim SA, Johnson RL, Sanmarco ME, Azen SP, Cashin-Hemphill L JAMA 1987 Jun 19;257:3233-40 [3295315]

Comparison of computer- and human-derived coronary angiographic end-point measures for controlled therapy trials. Mack WJ, Selzer RH, Pogoda JM, Lee PL, Shircore AM, Azen SP, Blankenhorn DH Arterioscler Thromb 1992 Mar;12:348-56 [1547194]

2 Fibrates

Trial	Treatments	Patients	Trials design and methods
bezafibrate vs placebo			
LEADER trial , 2000 n=783/785 follow-up: 5 ans	Bezafibrate: 400 mg/ jour pour les hommes avec cratininmie <135 micromole/litre versus placebo de mme aspect	Stade de la maladie : II.	Parallel groups Double aveugle

References

LEADER trial, 2000:

Tom Meade, Riaz Zuhrie, Claire Cook, Jackie Cooper on behalf of MRC Genral Practice Research Framework. Bezafibrate in men with lower extremity arterial disease: randomised controlled trial. BMJ 2002; 325: 1139-43

3 probucol

Trial	Treatments	Patients	Trials design and methods
probucol vs placebo			
PQRST , 1994 n=152/151 follow-up: 3 ans	Probucol 1 g / j pendant 3 ans versus placebo, de mme aspect(2 tablettes par jour)pendant 3 ans	Stade II: 70%	Parallel groups Double aveugle

References

PQRST, 1994:

Probucol Quantitative Regression Swedish Trial: new angiographic technique to measure atheroma volume of the femoral artery. Erikson U, Nilsson S, Stenport G Am J Cardiol 1988 Jul 25;62:44B-47B [3293416]

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Development of femoral atherosclerosis in hypercholesterolemic patients during treatment with cholestyramine and probucol/placebo: Probucol Quantitative Regression Swedish Trial (PQRST): a status report. Walldius G, Carlson LA, Erikson U, Olsson AG, Johansson J, Molgaard J, Nilsson S, Stenport G, Kaijser L, Lassvik C, et al Am J Cardiol 1988 Jul 25;62:37B-43B [3293415]

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The role of lipids and antioxidative factors for development of atherosclerosis. The Probucol Quantitative Regression Swedish Trial (PQRST). Walldius G, Regnstrom J, Nilsson J, Johansson J, Schafer-Elinder L, Moelgaard J, Hadell K, Olsson AG, Carlson LA Am J Cardiol 1993 Feb 25;71:15B-19B [8434556]

4 statins

Trial	Treatments	Patients	Trials design and methods
atorvastatin vs placebo			
Mohler III , 2003 n=240/114 follow-up: 1 an	Atorvastatine: 10 mg/ jour ou 80 mg/ jour pendant 12 mois (groupes 1 et 2). versus placebo	Stade de la madie : II , stable pendant au moins 6 mois.	Parallel groups Double aveugle
simvastatin vs placebo			
Mondillo , 2003 n=43/43 follow-up: 6 mois	simvastatine: 40 mg/ jour pendant 6 mois. versus placebo	Stade de la maladie: II.	Parallel groups Double aveugle
Aronow , 2003 n=34/35 follow-up: 1 an	simvastatine 40 mg/j versus placebo	Stade II	Parallel groups Non dterminable

continued...

Trial	Treatments	Patients	Trials design and methods
HPS (sub group) , 2002 n=10269/10267 follow-up: 5 ans	simvastatine 40 mg/ jour pendant 5 ans versus placebo	32.85% des patients prsentaient une artriopathie des membres infrieurs	Factorial plan Double aveugle

References

Mohler III, 2003:

Cholesterol reduction with atorvastatin improves walking distance in patients with peripheral arterial disease. Mohler ER 3rd, Hiatt WR, Creager MA Circulation 2003 Sep 23;108:1481-6 [12952839]

Mondillo, 2003:

Effects of simvastatin on walking performance and symptoms of intermittent claudication in hypercholesterolemic patients with peripheral vascular disease. Mondillo S, Ballo P, Barbati R, Guerrini F, Ammaturo T, Agricola E, Pastore M, Borrello F, Belcastro M, Picchi A, Nami R Am J Med 2003 Apr 1;114:359-64 [12714124]

Aronow , 2003:

Effect of simvastatin versus placebo on treadmill exercise time until the onset of intermittent claudication in older patients with peripheral arterial disease at six months and at one year after treatment. Aronow WS, Nayak D, Woodworth S, Ahn C Am J Cardiol 2003 Sep 15;92:711-2 [12972114]

HPS (sub group), 2002:

Amann W, Berg P, Gerbasch P, Gamain J, Raphael JH, Ubbink DT. Spinal cord stimulation in the treatment of non reconstructable stable critical leg ischaemia: results of the European peripheral vascular disease outcomes study (SCS-EPOS) European journal of vascular and endovascular surgery 26, 280-286 (2003).

Aung PP, Maxwell HG, Jepson RG, Price JF, Leng GC Lipid-lowering for peripheral arterial disease of the lower limb. Cochrane Database Syst Rev 2007 Oct 17;:CD000123 [17943736]

5 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.