

Clinical trials of cholesterol lowering intervention for cardiovascular prevention in patients with LDL elevation and without CHD

TrialResults-center www.trialresultscenter.org

1 diet

Trial	Treatments	Patients	Trials design and methods
diet vs usual diet			
Finnish Mental Hospital (Miettinen) , 1985 n=612/610 follow-up: 6.0 years	cholesterol-lowering diet (low in saturated fats and cholesterol and relatively high in polyunsaturated fats) versus usual diet	middle-aged institutionalized women without CHD	Cluster-randomized cross-over open, blind assessment Finland
Goteborg , 1986 n=10004/20028 follow-up: 10 years	multifactorial intervention programme versus no intervention	men, 47-55 years old at entry	Parallel groups open Sweden
Hjermann , 1981 n=604/628 follow-up: 6.5 years	diet versus usual diet	healthy, normotensive men at high risk of coronary heart disease	Parallel groups open Sweden
MRFIT , 1982 n=6428/6438 follow-up: 6.5 y	multifactor intervention program versus usual diet	high-risk men aged 35 to 57 years	Parallel groups open
Veterans Ad. (Dayton) , 1969 n=424/422 follow-up: 3.6 and 8 y	cholesterol lowering diet versus usual diet	men in domiciliary care, age>55, with or without CHD	Parallel groups double blind USA
WHO Collaborative , 1986 n=30489/26971 follow-up: 5.5 years	multifactorial prevention versus usual diet	middle-aged men	Parallel groups open Belgium, Italy, Poland, UK

References

Finnish Mental Hospital (Miettinen), 1985:

European collaborative trial of multifactorial prevention of coronary heart disease: final report on the 6-year results. World Health Organisation European Collaborative Group. Lancet 1986;1:869-72 [2870351]

Miettinen TA, Huttunen JK, Naukkarinen V, Strandberg T, Mattila S, Kumlin T, Sarna S Multifactorial primary prevention of cardiovascular diseases in middle-aged men. Risk factor changes, incidence, and mortality. JAMA 1985;254:2097-102 [4046137]

Miettinen M, Turpeinen O, Karvonen MJ, Pekkarinen M, Paavilainen E, Elosuo R Dietary prevention of coronary heart disease in women: the Finnish mental hospital study. Int J Epidemiol 1983;12:17-25 [6840954]

Goteborg, 1986:

Wilhelmsen L, Berglund G, Elmfeldt D, Tibblin G, Wedel H, Pennert K, Vedin A, Wilhelmsson C, Werk L The multifactor primary prevention trial in Gteborg, Sweden. *Eur Heart J* 1986;7:279-88 [[3720755](#)]

Hjermann, 1981:

Hjermann I, Velve Byre K, Holme I, Leren P Effect of diet and smoking intervention on the incidence of coronary heart disease. Report from the Oslo Study Group of a randomised trial in healthy men. *Lancet* 1981;2:1303-10 [[6118715](#)]

MRFIT, 1982:

Multiple risk factor intervention trial. Risk factor changes and mortality results. Multiple Risk Factor Intervention Trial Research Group. *JAMA* 1982;248:1465-77 [[7050440](#)]

Veterans Ad. (Dayton), 1969:

Dayton S, Pearce ML, Hashimoto S, Dixon WJ, Tomiyasu U. A controlled clinical trial of a diet high in unsaturated fat in preventing complications of atherosclerosis. *Circulation* 1969; 40(supp 2):1-55 [0]

WHO Collaborative, 1986:

European collaborative trial of multifactorial prevention of coronary heart disease: final report on the 6-year results. World Health Organisation European Collaborative Group. *Lancet* 1986;1:869-72 [[2870351](#)]

2 fibrates

Trial	Treatments	Patients	Trials design and methods
clofibrate vs placebo			
Cullen , 1974 n=20/20 follow-up: 2 years	clofibrate versus placebo		Parallel groups
WHO clofibrate , 1978 n=5331/5296 follow-up: 5.3 years	clofibrate 1.6 g daily versus olive oil	primary prevention, Hommes, de 30 59 ans	Parallel groups double blind Scotland, Hungary, Czech Republic
gemfibrozil vs placebo			
Helsinki (HHS) , 1987 n=2046/2035 follow-up: 5 years	gemfibrozil 1,2 g/d versus placebo	asymptomatic middle-aged men (40 to 55 years of age) with primary dyslipidemia (non-HDL cholesterol greater than or equal to 200 mg per deciliter [5.2 mmol per liter])	Parallel groups double blind Finland

References

Cullen, 1974:

WHO clofibrate, 1978:

, WHO cooperative trial on primary prevention of ischaemic heart disease with clofibrate to lower serum cholesterol: final mortality follow-up. Report of the Committee of Principal Investigators. *Lancet* 1984; 2:600-4 [[6147641](#)]

Heady JA, Morris JN, Oliver MF, WHO clofibrate/cholesterol trial: clarifications. *Lancet* 1992; 340:1405-6 [[1360101](#)]

Helsinki (HHS), 1987:

Manninen V, Elo MO, Frick MH, Haapa K, Heinonen OP, Heinsalmi P, Helo P, Huttunen JK, Kaitaniemi P, Koskinen P, et al, Lipid alterations and decline in the incidence of coronary heart disease in the Helsinki Heart Study. *JAMA* 1988; 260:641-51 [[3164788](#)]

Frick MH, Elo O, Haapa K, Heinonen OP, Heinsalmi P, Helo P, Huttunen JK, Kaitaniemi P, Koskinen P, Manninen V Helsinki Heart Study: primary-prevention trial with gemfibrozil in middle-aged men with dyslipidemia. Safety of treatment, changes in risk factors, and incidence of coronary heart disease. N Engl J Med 1987;317:1237-45 [3313041]

3 Probuco

Trial	Treatments	Patients	Trials design and methods
probuco vs control			
FATS Fukosawa (probuco) , 2002 n=82/81 follow-up: 2 years	probuco 500 mg/day versus diet alone	asymptomatic patients with hypercholesterolemia	Parallel groups open Japan

References

FATS Fukosawa (probuco), 2002:

Sawayama Y, Shimizu C, Maeda N, Tatsukawa M, Kinukawa N, Koyanagi S, Kashiwagi S, Hayashi J Effects of probuco and pravastatin on common carotid atherosclerosis in patients with asymptomatic hypercholesterolemia. Fukuoka Atherosclerosis Trial (FAST). J Am Coll Cardiol 2002 Feb 20;39:610-6 [11849859]

4 resins

Trial	Treatments	Patients	Trials design and methods
cholestyramine vs placebo			
LRC , 1984 n=1906/1900 follow-up: 7.4 years	cholestyramine 24 g daily versus placebo	asymptomatic middle-aged men with primary hypercholesterolemia (type II hyperlipoproteinemia)	Parallel groups double blind USA
colestipol vs placebo			
Gundersen , 1976 n=36/30 follow-up: 0.8 years	colestipol 10g twice daily versus placebo	hypercholesterolemic patients	Parallel groups double-blind
Ruoff , 1978 n=21/19 follow-up: 3.2 years	colestipol versus placebo	hypercholesterolemic patients	Parallel groups
Ryan , 1974 n=44/48 follow-up: 3.0 years	colestipol 15 g/day versus placebo	patients with hypercholesterolemia	Parallel groups
UCS (Dorr) , 1978 n=1149/1129 follow-up: 1.9 years	colestipol hydrochloride 32 mg/dl versus placebo	Hommes et femmes, >18 ans	Parallel groups double blind

References

LRC, 1984:

, The Lipid Research Clinics Coronary Primary Prevention Trial results. I. Reduction in incidence of coronary heart disease. JAMA 1984; 251:351-64 [6361299]

Gundersen, 1976:

Gundersen K, Cooper EE, Ruoff G, Nikolai T, Assenzo JR Cholesterol-lowering effect of colestipol hydrochloride given twice daily in hypercholesterolemic patients. Atherosclerosis 1976;25:303-10 [795441]

Ruoff, 1978:

Ruoff G Colestipol hydrochloride for treatment of hypercholesterolemia in a family practice: five-year study. J Am Geriatr Soc 1978;26:121-6 [624819]

Ryan, 1974:

Ryan JR, Jain AK, McMahon FG Long-term treatment of hypercholesterolemia with colestipol hydrochloride. Clin Pharmacol Ther 1975;17:83-7 [1091391]

UCS (Dorr), 1978:

Dorr AE, Gundersen K, Schneider JC Jr, Spencer TW, Martin WB, Colestipol hydrochloride in hypercholesterolemic patients—effect on serum cholesterol and mortality. J Chronic Dis 1978; 31:5-14 [346598]

5 statins

Trial	Treatments	Patients	Trials design and methods
lovastatin vs placebo			
AFCAPS/TexCAPS , 1998 n=3304/3301 follow-up: 5.2 years	lovastatin 20-40 mg/d versus placebo	men and women without clinically evident atherosclerotic cardiovascular disease with average total cholesterol (TC) and LDL-C levels and below-average high-density lipoprotein cholesterol (HDL-C) levels	Parallel groups double blind USA
pravastatin vs placebo			
WOSCOPS , 1995 n=3302/3293 follow-up: 4.9 years	pravastatin 40 mg daily versus placebo	men aged 45-64 yr with no history of myocardial infarction and with raised plasma cholesterol levels (LDL cholesterol of at least 155 mg/dL, total cholesterol of at least 252 mg/dL)	Parallel groups double blind Scotland

References

AFCAPS/TexCAPS, 1998:

Downs JR, Clearfield M, Weis S, Whitney E, Shapiro DR, Beere PA, Langendorfer A, Stein EA, Krueyer W, Gotto AM Jr, Primary prevention of acute coronary events with lovastatin in men and women with average cholesterol levels: results of AFCAPS/TexCAPS. Air Force/Texas Coronary Atherosclerosis Prevention Study. JAMA 1998; 279:1615-22 [9613910]

Cui Y, Watson DJ, Girman CJ, Shapiro DR, Gotto AM, Hiserote P, Clearfield MB Effects of increasing high-density lipoprotein cholesterol and decreasing low-density lipoprotein cholesterol on the incidence of first acute coronary events (from the Air Force/Texas Coronary Atherosclerosis Prevention Study). Am J Cardiol 2009;104:829-34 [19733719]

WOSCOPS, 1995:

Shepherd J, Cobbe SM, Ford I, Isles CG, Lorimer AR, MacFarlane PW, McKillop JH, Packard CJ, Prevention of coronary heart disease with pravastatin in men with hypercholesterolemia. West of Scotland Coronary Prevention Study Group. N Engl J Med 1995; 333:1301-7 [7566020]

A coronary primary prevention study of Scottish men aged 45-64 years: trial design. The West of Scotland Coronary Prevention Study Group. J Clin Epidemiol 1992;45:849-60 [1624967]

6 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.