

Clinical trials of lovastatin

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1 cardiovascular prevention

| Trial | Treatments | Patients | Trials design and methods |
|--|---|--|---|
| lovastatin vs placebo | | | |
| ACAPS , 1994 [NCT00000469] n=460/459 follow-up: 2.8 years | lovastatin 20mg daily versus placebo | men and women, 40 to 79 years old, with early carotid atherosclerosis and moderately elevated LDL cholesterol. | Factorial plan double blind USA |
| AFCAPS/TexCAPS (diabetic sub group) , 1998 n=84/71 follow-up: | lovastatin 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 |
| 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 |
| CCAIT , 1994 n=165/166 follow-up: 2 years | lovastatin begun at 20 mg/d and titrated to 40 and 80 mg during the first 16 weeks to attain a fasting low-density lipoprotein (LDL) cholesterol <or = 130 mg/dL versus placebo | patients with diffuse but not necessarily severe coronary atherosclerosis documented on a recent arteriogram and with fasting serum cholesterol between 220 and 300 mg/dL | Parallel groups double-blind Canada |
| CRISP 20mg , 1994 [NCT00000477] n=NA follow-up: 1 years | lovastatin 20mg daily versus placebo | elderly (mean 71y) with low-density lipoprotein cholesterol levels greater than 4.1 and less than 5.7 mmol/L | Parallel groups double blind |
| CRISP 40mg , 1994 [NCT00000477] n=NA follow-up: 1 years | lovastatin 40 mg daily versus placebo | elderly (mean 71y) with low-density lipoprotein cholesterol levels greater than 4.1 and less than 5.7 mmol/L | Parallel groups double blind |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|--|---|---|---|
| Excel , 1991 n=6582/1663 follow-up: 0.9 years | lovastatin (20 mg once daily, 40 mg once daily, 20 mg twice daily, or 40 mg twice daily) versus placebo | patients with moderate hypercholesterolemia | Parallel groups double blind |
| MARS , 1993 [NCT00116870] n=123/124 follow-up: 2.0y | lovastatin 80 mg/day versus placebo | patients, 37 to 67 years old, with total cholesterol ranging from 4.92 to 7.64 mmol/L (190 to 295 mg/dL) and angiographically defined coronary artery disease | Parallel groups double blind |
| Weintraub , 1994 n=203/201 follow-up: 0.5 years | lovastatin 40 mg orally twice daily versus placebo | patients undergoing PTCA | Parallel groups double blind |
| 65279;AFCAPS (women subgroup) , 1998 n=499/498 follow-up: 5.2 y | Lovastatin 2040 mg daily versus placebo | men and postmenopausal women without clinical evidence of cardiovascular disease (CVD) who had average low-density lipoprotein cholesterol and below average high-density lipoprotein cholesterol - subgroup of women | Parallel groups double blind US |
| lovastatin vs usual care | | | |
| CLAPT , 1999 n=112/114 follow-up: 2.0 years | lovastatin begun at 20 mg daily and titrated up to 80 mg daily versus usual care | patients undergoing PTCA | Parallel groups open (blind assesment) |
| Sahni , 1991 n=79/78 follow-up: 2 years | lovastatin 20-40mg/d versus conventional therapy alone | patients undergoing successful PTCA | Parallel groups open |

More details and results :

- cholesterol lowering intervention for cardiovascular prevention in patients with LDL elevation and without CHD at <http://www.trialresultscenter.org/go-Q5>
- cholesterol lowering intervention for cardiovascular prevention in diabetic patients at <http://www.trialresultscenter.org/go-Q6>
- cholesterol lowering intervention for cardiovascular prevention in elderly at <http://www.trialresultscenter.org/go-Q7>
- cholesterol lowering intervention for cardiovascular prevention in patients with prior MI or with CHD at <http://www.trialresultscenter.org/go-Q12>
- cholesterol lowering intervention for cardiovascular prevention in patients with other atherosclerotic localisation at <http://www.trialresultscenter.org/go-Q126>

- cholesterol lowering intervention for cardiovascular prevention in all chronic situations at <http://www.trialresultscenter.org/go-Q154>
- cholesterol lowering intervention for cardiovascular prevention in primary prevention at <http://www.trialresultscenter.org/go-Q241>
- cholesterol lowering intervention for cardiovascular prevention in women at <http://www.trialresultscenter.org/go-Q435>
- statins for cardiovascular prevention in secondary prevention at <http://www.trialresultscenter.org/go-Q689>
- statins for cardiovascular prevention in diabetic patients at <http://www.trialresultscenter.org/go-Q694>

References

ACAPS, 1994:

Furberg CD, Adams HP Jr, Applegate WB, Byington RP, Espeland MA, Hartwell T, Hunninghake DB, Lefkowitz DS, Probstfield J, Riley WA Effect of lovastatin on early carotid atherosclerosis and cardiovascular events. Asymptomatic Carotid Artery Progression Study (ACAPS) Research Group. *Circulation* 1994;90:1679-87 [7734010]

Rationale and design for the Asymptomatic Carotid Artery Plaque Study (ACAPS). The ACAPS Group. *Control Clin Trials* 1992;13:293-314 [1330434]

AFCAPS/TexCAPS (diabetic sub group), 1998:

Downs JR, Clearfield M, Weis S, Whitney E, Shapiro DR, Beere PA, Langendorfer A, Stein EA, Kruyer W, Gotto AM Jr *JAMA* 1998;279:1615-22 [9613910]

AFCAPS/TexCAPS, 1998:

Downs JR, Clearfield M, Weis S, Whitney E, Shapiro DR, Beere PA, Langendorfer A, Stein EA, Kruyer 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]

CCAIT, 1994:

Probstfield JL, Margitic SE, Byington RP, Espeland MA, Furberg CD Results of the primary outcome measure and clinical events from the Asymptomatic Carotid Artery Progression Study. *Am J Cardiol* 1995;76:47C-53C [7572686]

Waters D, Higginson L, Gladstone P, Kimball B, LeMay M, Lesprance J Design features of a controlled clinical trial to assess the effect of an HMG CoA reductase inhibitor on the progression of coronary artery disease. Canadian Coronary Atherosclerosis Intervention Trial Investigators Montreal, Ottawa, and Toronto, Canada. *Control Clin Trials* 1993;14:45-74 [8440094]

Waters D, Higginson L, Gladstone P, Kimball B, Le May M, Boccuzzi SJ, Lesprance J Effects of monotherapy with an HMG-CoA reductase inhibitor on the progression of coronary atherosclerosis as assessed by serial quantitative arteriography. The Canadian Coronary Atherosclerosis Intervention Trial. *Circulation* 1994;89:959-68 [8124836]

CRISP 20mg, 1994:

LaRosa JC, Applegate W, Crouse JR 3rd, Hunninghake DB, Grimm R, Knopp R, Eckfeldt JH, Davis CE, Gordon DJ Cholesterol lowering in the elderly. Results of the Cholesterol Reduction in Seniors Program (CRISP) pilot study. *Arch Intern Med* 1994;154:529-39 [8122946]

Stoy DB, Curtis RC, Dameworth KS, Dowdy AA, Hegland J, Levin JA, Sousoulas BG The successful recruitment of elderly black subjects in a clinical trial: the CRISP experience. Cholesterol Reduction in Seniors Program. J Natl Med Assoc 1995;87:280-7 [7752281]

CRISP 40mg, 1994:

LaRosa JC, Applegate W, Crouse JR 3rd, Hunninghake DB, Grimm R, Knopp R, Eckfeldt JH, Davis CE, Gordon DJ Cholesterol lowering in the elderly. Results of the Cholesterol Reduction in Seniors Program (CRISP) pilot study. Arch Intern Med 1994;154:529-39 [8122946]

Excel, 1991:

Bradford RH, Shear CL, Chremos AN, Dujovne C, Downton M, Franklin FA, Gould AL, Hesney M, Higgins J, Hurley DP Expanded Clinical Evaluation of Lovastatin (EXCEL) study results. I. Efficacy in modifying plasma lipoproteins and adverse event profile in 8245 patients with moderate hypercholesterolemia. Arch Intern Med 1991;151:43-9 [1985608]

MARS, 1993:

Blankenhorn DH, Azen SP, Krams DM, Mack WJ, Cashin-Hemphill L, Hodis HN, DeBoer LW, Mahrer PR, Masteller MJ, Vailas LI, Alaupovic P, Hirsch LJ Coronary angiographic changes with lovastatin therapy. The Monitored Atherosclerosis Regression Study (MARS). Ann Intern Med 1993;119:969-76 [8214993]

Weintraub, 1994:

Weintraub WS, Boccuzzi SJ, Klein JL, Kosinski AS, King SB 3rd, Ivanhoe R, Cedarholm JC, Stillabower ME, Talley JD, DeMaio SJ Lack of effect of lovastatin on restenosis after coronary angioplasty. Lovastatin Restenosis Trial Study Group. N Engl J Med 1994;331:1331-7 [7935702]

65279;AFCAPS (women subgroup) , 1998:

Downs JR, Clearfield M, Weis S, Whitney E, Shapiro DR, Beere PA, Langendorfer A, Stein EA, Kruyer 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]

Clearfield M, Downs JR, Weis S, Whitney EJ, Kruyer W, Shapiro DR, Stein EA, Langendorfer A, Beere PA, Gotto AM Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS): efficacy and tolerability of long-term treatment with lovastatin in women. J Womens Health Gend Based Med 2001;10:971-81 [11788107] 10.1089/152460901317193549

CLAPT, 1999:

Kleemann A, Eckert S, von Eckardstein A, Lepper W, Schernikau U, Gleichmann U, Hanrath P, Fleck E, Neiss A, Kerber S, Assmann G, Breithardt and the CLAPT Study Effects of lovastatin on progression of non-dilated and dilated coronary segments and on restenosis in patients after PTCA. The cholesterol lowering atherosclerosis PTCA trial (CLAPT) Eur Heart J 1999;20:1393-406 [10487800]

Sahni, 1991:

Sahni R, Maniet AR, Voci G, Banka VS Prevention of restenosis by lovastatin after successful coronary angioplasty. Am Heart J 1991;121:1600-8 [2035374]

2 diabetes type 2

| Trial | Treatments | Patients | Trials design and methods |
|-----------------------|------------|----------|---------------------------|
| lovastatin vs placebo | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---------------------------------|--|---------------------------------|
| AFCAPS/TexCAPS (diabetic sub group) , 1998 n=84/71 follow-up: | lovastatin 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 |

More details and results :

- cholesterol lowering intervention for diabetes type 2 in diabetic patients with or without hypercholesterolemia at <http://www.trialresultscenter.org/go-Q85>
- cholesterol lowering intervention for diabetes type 2 in primary prevention at <http://www.trialresultscenter.org/go-Q720>

References

AFCAPS/TexCAPS (diabetic sub group), 1998:

Downs JR, Clearfield M, Weis S, Whitney E, Shapiro DR, Beere PA, Langendorfer A, Stein EA, Krueyer W, Gotto AM Jr JAMA 1998;279:1615-22 [9613910]

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