

# Clinical trials of statins for cardiovascular prevention in diabetic patients

TrialResults-center [www.trialresultscenter.org](http://www.trialresultscenter.org)

## 1 statins

| Trial  | Treatments                                       | Patients  | Trials design and methods                       |
|--|--|---|---|
| <b>atorvastatin vs placebo</b>   |  |   |   |
| <b>ASPEN , 2006</b><br>n=1211/1199<br>follow-up: 4 year  | atorvastatin 10mg<br>versus<br>placebo           | subjects with type 2 diabetes and LDL cholesterol levels below contemporary guideline targets   | Parallel groups<br>double blind<br>14 countries |
| <b>CARDS , 2004</b><br>[NCT00327418]<br>n=1429/1412<br>follow-up: 3.9 years                    | atorvastatin 10mg/d<br>versus<br>placebo         | patients with type 2 diabetes without high concentrations of LDL-cholesterol and at least one of the following: retinopathy, albuminuria, current smoking, or hypertension.   | Parallel groups<br>double blind<br>UK, Irelande |
| <b>lovastatin vs placebo</b>   |  |   |   |
| <b>CRISP 20mg , 1994</b><br>[NCT00000477]<br>n=NA<br>follow-up: 1 years                        | lovastatin 20mg daily<br>versus<br>placebo       | elderly (mean 71y) with low-density lipoprotein cholesterol levels greater than 4.1 and less than 5.7 mmol/L  | Parallel groups<br>double blind                 |
| <b>CRISP 40mg , 1994</b><br>[NCT00000477]<br>n=NA<br>follow-up: 1 years                        | lovastatin 40 mg daily<br>versus<br>placebo      | elderly (mean 71y) with low-density lipoprotein cholesterol levels greater than 4.1 and less than 5.7 mmol/L  | Parallel groups<br>double blind                 |
| <b>pravastatin vs placebo</b>  |  |   |   |
| <b>PHYLLIS , 2004</b><br>n=508<br>follow-up: 2.6 y   | pravastatin (40 mg per day)<br>versus<br>placebo | hypertensive, hypercholesterolemic patients with asymptomatic carotid atherosclerosis   | Factorial plan<br>double-blind<br>Italy         |
| <b>rosuvastatin vs placebo</b>   |  |   |   |
| <b>METEOR , 2007</b><br>[NCT00225589]<br>n=702/282<br>follow-up:                               | rosuvastatin 40mg daily<br>versus<br>placebo     | individuals, with either age (mean, 57 years) as the only coronary heart disease risk factor or a 10-year Framingham risk score of less than 10% , modest CIMT thickening (1.2-<3.5 mm), and elevated LDL cholesterol | Parallel groups<br>double-blind<br>USA, Europe  |
| <b>simvastatin vs placebo</b>  |  |   |   |
| <b>HPS (diabetic primary prevention sub group) , 2003</b><br>n=1455/1457<br>follow-up: 5 years | simvastatin 40 mg/d<br>versus<br>placebo         | adults (aged 40-80 years) with diabetes (primary prevention subgroup)   | Parallel groups<br>double blind<br>UK           |

## References

### **ASPEN, 2006:**

Knopp RH, d'Emden M, Smilde JG, Pocock SJ Efficacy and safety of atorvastatin in the prevention of cardiovascular end points in subjects with type 2 diabetes: the Atorvastatin Study for Prevention of Coronary Heart Disease Endpoints in non-insulin-dependent diabetes mellitus (ASPEN). *Diabetes Care* 2006;29:1478-85 [[16801565](#)]

### **CARDS, 2004:**

Colhoun HM, Betteridge DJ, Durrington PN, Hitman GA, Neil HA, Livingstone SJ, Thomason MJ, Mackness MI, Charlton-Menys V, Fuller JH Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS): multicentre randomised placebo-controlled trial. *Lancet* 2004 Aug 21;364:685-96 [[15325833](#)]

### **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](#)]

### **PHYLLIS, 2004:**

Zanchetti A, Crepaldi G, Bond MG, Gallus G, Veglia F, Mancia G, Ventura A, Baggio G, Sampieri L, Rubba P, Sperti G, Magni A Different effects of antihypertensive regimens based on fosinopril or hydrochlorothiazide with or without lipid lowering by pravastatin on progression of asymptomatic carotid atherosclerosis: principal results of PHYLLIS—a randomized double-blind trial. *Stroke* 2004;35:2807-12 [[15514192](#)]

### **METEOR, 2007:**

### **HPS (diabetic primary prevention sub group), 2003:**

## 2 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.