

God Bless America
Best Health Care Medical Group, Inc.
Professor Mike Mirahmadi, M.D.

Diplomate, American Board of Internal Medicine & Nephrology
Clinical Professor of Medicine at UCLA

Statins and Primary Prevention for Patients at High Risk for Heart Disease

The benefit, if any, is very small.

Statins — which clearly confer an all-cause mortality benefit in patients with known cardiovascular disease (CVD) — are prescribed extensively for primary prevention in patients at high CVD risk but without CVD. Two groups of investigators examined evidence for this practice.

European investigators combined results for only high-risk patients without known CVD from 11 randomized controlled trials, including some previously unpublished data from the original investigators, to assess all-cause mortality in 65,000 patients (age range, 51–75). During average follow-up of nearly 4 years, the mean LDL cholesterol level was 134 mg/dL in placebo recipients and 94 mg/dL in statin recipients. Nearly 2800 deaths occurred, with about 100 fewer deaths in the treated group, for a risk ratio of 0.91 (roughly 7 fewer deaths per 10,000 person-years of treatment); the difference was not significant (95% confidence interval, 0.83–1.01).

In a related article, several authors critiqued the JUPITER study, which showed a significant benefit from primary prevention with rosuvastatin in patients without known CVD but with high-sensitivity C-reactive protein (hsCRP) levels ([JW Gen Med Dec 29 2008](#)). Among the authors' criticisms are (1) several secondary outcomes were used as justification for stopping the trial early when only a few major clinical events had occurred; (2) the apparent convergence of the all-cause mortality curves when the trial was stopped suggests that longer follow-up would have eliminated between-group differences; (3) an unexpectedly low mortality rate from CVD, as well as an unexpectedly low case-fatality rate from myocardial infarction at the time of early termination, suggests the potential for undetected bias; (4) manufacturer involvement in the conduct of the study was substantial; and (5) 9 of the 14 JUPITER investigators had potential conflicts of interest.

Comment: Unsurprisingly, these studies have created a firestorm of debate. Authors of one editorial sum up the JUPITER controversy by noting that nothing can be said about the value of hsCRP for primary prevention with statins when patients with low hsCRP levels were not included in the trial, that stopping a trial early tends to exaggerate the apparent benefits and minimize the potential harms of a study, and that these results should not distract us from focusing on known risk factors and benefits of lifestyle modification. Another editorialist sums up the issue by saying that "in the short term, for true primary prevention, the benefit, if any, is very small."

— [Thomas L. Schwenk, MD](#)

Published in [Journal Watch General Medicine July 15, 2010](#)Citation(s):

Ray KK et al. Statins and all-cause mortality in high-risk primary prevention: A meta-analysis of 11 randomized controlled trials involving 65 229 participants. *Arch Intern Med* 2010 Jun 28; 170:1024. (<http://dx.doi.org/10.1001/archinternmed.2010.182>)

435 N. Bedford, Suite 312
Beverly Hills, CA 90210
Tel: 310-858-5090
Fax: 310-276-5508

3392 Motor Ave.
Los Angeles, CA 90034
Tel: (310) 202-1133
Fax: (310) 202-1139

Please visit our website:
<http://mirahmadi.com>

Email: Mike@Mirahmadi.com