Phytosterols, red yeast rice, and lifestyle changes instead of statins: a randomized, double-blinded, placebo-controlled trial.

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Phytosterols, red yeast rice, and lifestyle changes instead of statins: a randomized, double-blinded, placebo-controlled trial.

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Abstract

BACKGROUND: Many patients who refuse or cannot tolerate statin drugs choose alternative therapies for lipid lowering.

OBJECTIVES: This study aimed to determine the lipid-lowering effects of phytosterol tablets and lifestyle change (LC) on top of red yeast rice (RYR) therapy in patients with a history of statin refusal or statin-associated myalgias.

DESIGN: A total of 187 participants (mean low-density lipoprotein cholesterol [LDL-C], 154 mg/dL) took RYR 1800 mg twice daily and were randomized to phytosterol tablets 900 mg twice daily or placebo. Participants were also randomized to a 12-week LC program or usual care (UC). Primary end point was change in LDL-C at 12, 24, and 52 weeks. Secondary end points were effect on other lipoproteins, high-sensitivity C-reactive protein, weight, and development of myalgia.

RESULTS: Phytosterols did not significantly improve LDL-C at weeks 12 (P = .54), 24 (P = .67), or 52 (P = .76) compared with placebo. Compared with the UC group, the LC group had greater reductions in LDL-C at weeks 12 (-51 vs -42 mg/dL, P = .006) and 24 (-48 vs -40 mg/dL, P = .034) and was 2.3 times more likely to achieve an LDL-C <100 mg/dL (P = .004). The LC group lost more weight for 1 year (-2.3 vs -0.3 kg, P < .001). All participants took RYR and had
significant decreases in LDL-C, total cholesterol, triglycerides, high-sensitivity C-reactive protein, and an increase in high-density lipoprotein cholesterol for 1 year when compared with baseline ($P < .001$). Four participants stopped supplements because of myalgia.

**CONCLUSIONS:** The addition of phytosterol tablets to RYR did not result in further lowering of LDL-C levels. Participants in an LC program lost significantly more weight and were more likely to achieve an LDL-C $<100$ mg/dL compared with UC.