

A Placebo-Controlled Trial of a Proprietary Lipid-Lowering Nutraceutical Supplement in the Management of Dyslipidemia

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Aims

This study was designed to determine the tolerability and overall effectiveness of a proprietary multi-ingredient, lipid-lowering supplement in subjects with dyslipidemia.

Method

40 subjects were recruited for a single-center, double-blind, randomized, placebo-controlled trial. Study participants were recruited between December 2014 and March 2015. Initial screening included taking a medical history, physical examination, renal and hepatic function, serum lipid concentrations, serum electrolytes, complete blood counts, and urinalysis.

The study’s 40 patients were randomly assigned to receive either the proprietary multi-ingredient lipid-lowering supplement (PMILLS) or placebo. The trial consisted of a screening visit, a two-week run-in, and a four-month treatment period.

Samples were taken at baseline, one month, and four months of treatment.

Primary Outcomes

Compared to the participants who received placebo, those receiving the PMILLS had significant reductions in total cholesterol, LDL-C, and VLDL-C at both one and four months (see Figures 1, 2, and 3). LDL-P decreased at four months in the PMILLS group, while no change was observed in the placebo group. Total LDL-II and IV particle number (LDL-P), an important indicator of LDL particle size. After treatment, LDL-P was significantly decreased in the PMILLS group, whereas no change was observed in the placebo group (see Figure 4). Similar between-group changes were also observed for Apo-lipoprotein B and triglycerides (see Figures 5 and 6).

Secondary Outcomes

Diastolic blood pressure decreased from 72.4 ± 9 mmHg to 68.1 ± 11 mmHg in the PMILLS group, while no change was observed in the placebo group. Total LDL-III and IV particle number (LDL-P), an important indicator of LDL particle size.

Baseline vs 4 mos

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