A PLACEBO-CONTROLLED TRIAL OF A PROPRIETARY LIPID-LOWERING NUTRACEUTICAL SUPPLEMENT IN THE MANAGEMENT OF DYSLIPIDEMIA

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There is an ever growing emergence in the popularity of patient-driven care. As this health and wellness model grows, inquiries into diet, lifestyle, and supplemental approaches will continue to become a focal point for the healthcare consumer. Because of this, the aim of this study is to determine the tolerability, and overall effectiveness of a proprietary multi-ingredient lipid-lowering supplement in subjects with dyslipidemia. Forty participants 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 a physical examination, renal and hepatic function, serum lipid, serum electrolytes, complete blood counts, and urine analysis. The 40 participants were randomly assigned to receive either the proprietary multi-ingredient lipid-lowering supplement (PMILLS) n= 20 or placebo n= 20. 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. Results from the trial showed that the PMILLS significantly reduced total cholesterol (TC), low density lipoprotein (LDL-C), very low density lipoprotein (VLDL-C), oxidized LDL (oxLDL), Apo-lipoprotein B, triglycerides (TG), LDL particle number (LDL-P), heart rate, and diastolic blood pressure compared to placebo at one month and four months. The PMILLS significantly increased high density lipoprotein (HDL) particle number (HDL-P), and low density lipoprotein (LDL) particle size from dense type III and IV to larger type I and II LDL particle, compared to placebo at one month and four months. In addition, the PMILLS significantly reduced high sensitivity C-reactive protein (hs-CRP), tumor necrosis alpha (TNF-α), and interleukin 6 (IL-6) within the treatment group from baseline. There were no adverse effects noted in the treatment group after four months of supplementation. The present study demonstrates this PMILLS improves all relevant lipid parameters, such as particle numbers and particles sizes, as well as showing a significant reduction in inflammatory markers linked to cardiovascular health. With such combined changes in lipids, lipid sub-fractions, and inflammation, which are considered among the most effective means of reducing coronary heart disease (CHD), this PMILLS represents a new addition to safe and effective lipid-modifying strategies.