Combined Treatment with Dif1stat®and Diet Reduce Plasma Lipid Indicators of Moderate Hypercholesterolemia More Effectively than Diet Alone: A Randomized Trial in Parallel Groups.

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Abstract An open-labeled randomized trial with parallel groups was carried out to study the effects of Dif1stat® (Monascus purpureus–Linear aliphatic alcohols–Niacin) in the treatment of primary moderate hypercholesterolemia.

The trial lasted 8 months. The patients, males and females, were assigned to two groups: A (#130), treated with diet, and B (#110) submitted to diet + Dif1stat®.

After 4 months, group A did not show significant changes in Total cholesterol (TC), LDL-cholesterol (LDLC), HDL-cholesterol (HDLC) or non-HDL-cholesterol (non-HDLC). The same group, showed a reduction in TC (–22%), LDLC (–30%) and non-HDLC (–27%) after 8 months (P≤ 0.001).

After 4 months, TC (–21.3%), LDLC (–29%), and non-HDLC (–26%) were significantly lowered in group B (P≤ 0.001). In group B, TC, LDLC and non-HDLC showed a further reduction after 8 months: –29.4, –38 and –37%, respectively (P≤ 0.001). Even triglycerides (TG) decreased significantly (–33%) (P≤ 0.001).

After 8 months, group B showed a significant reduction of TG (–33%) (P≤ 0.001), when compared to group A. Some safety parameters were significantly reduced in both groups: AST and c-GT in group A after 4 and 8 months, as well as ALT, AST and c-GT in group B after 8 months (P≤ 0.001).

Dif1stat®, given with a suitable diet, was well tolerated in the long-term and induced an anti-atherogenic plasma lipid and lipoprotein profile, in patients with moderate hypercholesterolemia.