New Specialized Food Product

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Objectives: Aim of the study was to assess efficacy of new specialized food product "SPP2" in patients with non-alcoholic steatohepatitis (NASH).

Methods: New specialized food product (SPP2) was developed based on literature data on the efficacy of biologically active compounds in pathogenesis of NASH. It contains: protein, fat, ω-3 PUFAs, carbohydrates, soluble fibre, coenzime Q_{10}, L-carnitine, α-lipoic acid, vitamins (A, B_1, B_2, B_6, PP, B_{12}, D_3, C, K), phospholipids. Patients with NASH (per EASL guidelines), were invited to participate in the study and were randomized either to receive iso-caloric diet (based on the data of indirect caloriemetry) alone (ICD) or iso-caloric diet and SPP2 (SPP2). Repeated examinations of body composition with bioimpedance and blood tests were performed at baseline (BL) and after 14 days (EOT) of treatment. The patients were advised to follow usual physical activity during the study. Non-parametric statistics was used to compare BL and EOT characteristics in the groups.

Results: The data of examination of 25 subjects were available. The ICD ($n = 8$) and SPP2 ($n = 17$) groups did not differ by demographic and baseline characteristics. The use of SPP2 allowed to achieve better control of weight in SPP2 group (mean $\pm$ SD): 117.5 $\pm$ 30.1 kg/m^2 at BL vs 114.9 $\pm$ 28.8 kg/m^2 at EOT, $P < 0.01$) than in ICD (106.7 $\pm$ 22.1 at BL vs 104.0 $\pm$ 16.8 kg/m^2 at EOT, $P = 0.07$). In SPP2 group significant decrease of cholesterol (5.3 $\pm$ 1.3 mmol/L at BL vs 4.6 $\pm$ 1.3 mmol/L, $P = 0.003$), low density lipoproteids (3.7 $\pm$ 1.0 mmol/L at BL vs 3.3 $\pm$ 1.0 at EOT, $P = 0.009$), and HOMA-IR (6.1 $\pm$ 3.2 vs 3.2 $\pm$ 1.5, $P = 0.04$) was achieved, while in ICD these parameters remained unchanged. While ALT and AST decreased in both groups, significant decrease in alkaline phosphatase and gamma-GT was found only in SPP2 group.

Conclusions: New specialized food product "SPP2" in combination with iso-caloric diet lead to greater decrease of weight, than iso-caloric diet alone. It helps to achieve faster improvement of blood lipid profile and insulin resistance.

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