

### Clinical Safety and Tolerability of New Specialized Food Product

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**Objectives:** The use of specialized food products may increase efficacy of treatment in patients with non-alcoholic steatohepatitis (NASH). The aim of the study was to assess clinical safety and tolerability of newly developed specialized food product “SPP2” in patients with non-alcoholic steatohepatitis.

**Methods:** New specialized food product (SPP2) was developed based on literature data on the efficacy of active biological compounds on pathogenesis of NASH. It contains: protein, fat,  $\omega$ -3 PUFAs, carbohydrates, soluble fibre, Coenzyme Q10, L-carnitine,  $\alpha$ -lipoic acid, vitamins (A, B1, B2, B6, PP, B12, D3, C, K), phospholipids. The test batch of the product passed laboratory control for biological and toxicological safety. The study was approved by LEC and registered (NCT04308980). Patients with NASH (per EASL), were invited to participate and were randomized to receive iso-caloric diet alone (ICD) or iso-caloric diet and SPP2 (SPP2). Energy value of the diet was amended by calorie content of SPP2. The patients were advised to follow usual physical activity and report any adverse events (AE) occurred

during the study. Organoleptic assessment with the use of 5-point Likert scale and repeated blood tests on chemistry and hematology were performed at baseline (BL) and after 14 days (EOT) of treatment. Non-parametric statistics was used for the analysis

**Results:** One subject was lost to follow-up in ICD group and one postponed the use of SPP2 due to the not related to safety reasons. The data of 25 subjects were available for the final analysis. The ICD ( $n = 8$ ) and SPP2 ( $n = 17$ ) groups did not differ by demographic and baseline characteristics. Adherence to diet was 88% in ICD and 92% in SPP2 groups,  $p = 0.7$ . Compliance with SPP was 97%. No serious adverse events occurred during the study. Organoleptic assessment of SPP2 initially: appearance (Mean  $\pm$  SD)  $3.9 \pm 0.83$  points; color  $4.0 \pm 0.5$ ; aroma  $3.6 \pm 0.9$ ; texture  $3.7 \pm 0.8$ ; taste  $3.9 \pm 0.7$ ; resulting in a mean score  $3.9 \pm 0.4$  point at BL. No dissatisfaction revealed at EOT: the mean organoleptic score was  $4.2 \pm 0.7$  points ( $P = 0.07$ ). No laboratory AEs occurred.

**Conclusions:** New specialized food product “SPP2” in combination with iso-calorie diet is safe and well-tolerated by patients with NASH.

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