SPECIALIZED FOOD PRODUCT "SPP1" IMPROVES EFFICACY OF ISO-CALORIE DIET IN PATIENTS WITH NON-ALCOHOLIC STEATOHEPATITIS

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Background & Aims: Diet is supposed a first-line treatment for non-alcoholic steatohepatitis (NASH); however, there is a lack of biotechnological, specialized food products approved for clinical use in these patients. The **aim** of the study was to assess efficacy of developed specialized food product "SPP1" in combination with iso-calorie diet in patients with NASH.

Methods: Medical and technical requirements for the composition of a specialized food product ("SPP1") were developed based on the literature data, supporting efficacy of certain ingredients. Based on this, we made a recipe for a product's, that contains (% of the recommended daily allowances): protein-8%; fat-7% (including ω-3 PUFA-40%); soluble dietary fiber-160%; phospholipids-25%; alpha-lipoic acid-33%; betaine-10%; minerals-13%-44%; vitamins (A, E, D3, K1, C, B1, B2, B6, B12, PP, Folic acid, Pantothenic acid, Biotin) 24%-140%. The investigational party of "SPP1" was produced at laboratory of Food Biotechnology and Specialized Products. It sucessfully passed testing for hygienic safety and organoleptic qualities. The sudy of "SPP1" efficacy was approved by LEC and was appropriatly registered (**NCT04308980**). Main inclusion criteria were willingness to participate (written ICF), confirmed diagnosis of NASH (per EASL guidelines). Participants were randomized into 1 of the groups: ID (received **i**socaloric **d**iet, based on REE assessed with indirect calorimetry (Quarck RMR, Cosmed, Italy)), and "ID+SPP1" group, received ID and 2 portions of "SPP1" a day for 14 days (energy value of ID was amended for calorie value of "SPP1". Repeated measurements (baseline vs those on the 15th day of the study) of body composition (InBody, South Korea), and blood chemistry were used for efficacy analysis. No change in concomitant medications was allowed 1 month before the study and along it. Non-parametric statistics was used for data comparison.

Results: The data of 20 subjects (12 in ID+"SPP1" and 8 in ID group) served a source for the study. The groups were comparable by age, sex, and body mass index (BMI). The product was well tolerated; no serious adverse events were registered during the study. In contrast to ID group, those received "SPP1" demonstrated greater decrease of weight and body fat loss (figure 1). In both groups, we found a trend for ALT and AST decrease; however, it was not statistically significant neither in ID, nor in ID+"SPP1" group.

Conclusion: The results of this pilot study suggest that the new specialized food product "SPP1" is safe, and well tolerated by patients with NASH. In combination with isocaloric diet, it may increase efficacy of weight (and especially fat) loss. The results required assessment in larger cohorts.

Assessed parameter	ID+SPP1, n=12		*P*	ID (control), n=8		*P*
	Baseline Mean±SD	EOT Mean±SD		Baseline Mean±SD	EOT Mean±SD	
Weight, kg	110.6±16.1	107.8±15.5	0.002	106.7±22.1	103.7±20.8	0.07
BMI, kg/m^2	38.7±5.4	37.7±5.1	0.003	38.9±7.2	37.9±7.3	0.08
Body fat, kg	50.2±10.7	48.5±10.8	0.002	48.9±11.4	46.8±11.6	0.07
ALT, IU/mL	81.1±28.2	73.4±38.1	0.3	60.0±26.3	43.8±30.1	0.1
AST, IU/mL	61.5±29.2	53.6±26.3	0.16	41.8±20.1	32.4±15.6	0.07

BMI – body mass index; EOT – end of treatment (after 14 days of either isocaloric diet, or diet+specialized food product); SD – standard deviation; ID – group received isocaloric diet alone; ID+SPP1 – group received isocaloric diet and specialized food product "SPP1"

Figure 1: Efficacy of "SPP1" in treatment of patients with NASH.

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