

## Effects of very-low-calorie diet on body composition, metabolic state, and genes expression: a randomized double-blind placebo-controlled trial

### Effetti di una dieta a basso apporto di calorie sulla composizione corporea, lo stato metabolico e l'espressione genica: un trial randomizzato in doppio cieco controllato con placebo

**Objective:** very low-calorie diets (VLCDs, < 800 kcal day<sup>-1</sup>) and Ketogenic diet (KD) are generally used as part of integrated intervention, medical monitoring and a program of lifestyle modification, to improve a multitude of clinical states. The effect of three different very low calories KD (VLCKD), with (VLCKD1) or without (VLCKD2,3) synthetic amino acid replacement of the 50% protein intake, were analyzed after weight loss.

**Patients and methods:** the clinical study used a cross-over randomized double-blind placebo-controlled trial. Obese subjects, who were eligible for the study, were randomly (R) divided into three groups: one intervention group (IG) and two control groups (CG1 and CG2). We comprehensively analyzed body composition, serum metabolites, superoxide dismutase (SOD1), nuclear factor kappa-light-chain-enhancer of activated B cells (NfκB), Chemokine (C-C Motif) Ligand and 2 (CCL2) gene expression.

**Results:** after VLCKDs a significant decrease in BMI was observed. TBF (kg) significantly decrease after VLCKD1 and VLCKD3. After VLCKD2, a reduction of waist circumference ( $p = 0.02$ ), FM L2-L5 ( $p < 0.05$ ) was observed. After VLCKD1 reduction of IMAT ( $p = 0.00$ ), LDL-C ( $p = 0.00$ ) and HDL-C ( $p = 0.00$ ) were observed. No significant changes of GH, ESR, and fibrinogen were highlighted. CRP ( $p = 0.02$ ) reduced significantly after VLCKD3. Significant modulation of SOD1 expression ( $p = 0.009$ ), CRP and decrease of glucose levels ( $p = 0.03$ ) were obtained after VLCKD3.

**Conclusion:** this is the first study that analyzes comprehensively body composition, metabolic profile, and inflammation and oxidative stress genes expression after VLCKD. Our results show the efficacy of VLCKD with synthetic aminoacidic protein replacement, for the reduction of cardiovascular risk, without the development of sarcopenia and activation of inflammatory and oxidative processes.

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