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**Antioxidant effects of a hydroxytyrosol-based pharmaceutical formulation on body composition, metabolic state, and gene expression: a randomized double-blinded, placebo-controlled crossover trial.**

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Hydroxytyrosol (3,4 dihydroxyphenylethanol; 3,4-DHPEA or HT), the most abundant phenolic compound in extra virgin olive oil (EVOO) plays a significant role in cardiovascular diseases (CVDs) protection and its metabolites are able to protect from the endothelial dysfunction commonly present in atherosclerosis. This randomized double-blinded, placebo-controlled crossover trial study was carried out to determine the effect in healthy volunteers of two gastro-resistant capsules containing 15mg/day of HT, for a 3-week period (HTT). Evaluation of nutritional, serum metabolites, oxidative stress biomarkers and gene expression of 9 genes related to oxidative stress, inflammation and CVDs was performed. Oxidation biomarkers like thiols groups ($p$= 0.000), total antioxidant status (TAS) ($p$= 0.00), superoxide dismutase-1 (SOD1) ($2^{-\Delta\Delta Ct}$ = 3.7) and plasma concentration of HT (2.83 mg $mL^{-1}$) were significant increased, while nitrite ($p$= 0.00), nitrate ($p$= 0.001) and malondialdehyde (MDA) ($p$= 0.02) were drastically reduced after HTT. A significant reduction of body fat mass percentage ($p$= 0.01), suprailiac skinfold ($p$= 0.01) and weight ($p$= 0.04; Δ%= -0.46%) was observed after HTT. Results show that regular intake of 15 mg/day of HT changed body composition parameters, modulated anti-oxidant profile and the expression of inflammation and oxidative-stress-related genes. However, it is advisable a personalization of HT doses in order to exert its health benefits in CVDs prevention and protection of LDL-C particles from oxidative damage.