Health effects of Biostimulans lettuce in Human (NUTRIWEED23)

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The aim of the project is to study the influence of Biostimulants Lettuce crops on a healthy population in order to assess influence on hematological parameters and specific metabolism (glucose, lipid, iron, bone) and gut and lipid hormones. Secondary outcome will be to find out micronutrient presence in urine and serum in order to evaluate vegetables as biocarrier. The use of biostimulants in modern agriculture has rapidly expanded in recent years, owing to their beneficial effects on crop yield and product quality, which have come under the scope of intensive research.

The present project aims to investigate the benefits of biostimulants lettuce in a cohort of healthy individuals. Biostimulants are organic and inorganic compounds or microorganisms that when applied to plants can enhance plants' growth, yield, and tolerance to stress Specifically, participants will be fed with biostimulated lettuce in order to study the influence on hematological parameters.

 The healthy group will eat 100 grams of Lettuce (control group) and 100 grams of Biostimulated lettuce (intervention group) with weed or saline and collect plasma and urine samples after 15 days. Each subject will be subjected to two venous blood samples taken at the beginning of the observation and at the end. The samples obtained will be transported in certified containers for the safe transport of biological samples, and, subsequently, processed by the experimenters at the laboratories of the Molecular Biology section of the University of Palermo. Serum and plasma will be obtained from each blood sample. All information thus obtained will be recorded in a database in which each person will be identified with a numerical code, in order to comply with current privacy regulations. Body weight, Barefoot standing height, Body mass index, Body composition will be measured in the different groups of study. Samples will be analyzed and compared for glucose, albumin, total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, uric acid, creatinine, AST, ALT, γ-GT, ALP, bilirubin, Ferritin, free Iron, transferrin, total proteins, Magnesium, Calcium, insulin, osteocalcin, hematocrit, hs-CRP, TSH, FT3, FT4. Bone metabolism (Osteocalcin, parathyroid hormone, CTX, Calcitonin), Vitamin D Calcium, Phosphate, Potassium, gastric hormones (GIP, GLP1, GLP2, ghrelin, glucagon, PYY, CCK, leptin, resistin). The Outcome Measures will be Body weight, Barefoot standing height, Body mass index, Body composition by impedance analysis will be measured in the groups of study. Blood samples will be collected from the different groups of study and will be analyzed for for glucose, albumin, total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, uric acid, creatinine, AST, ALT, γ-GT, ALP, bilirubin, Ferritin, free Iron, transferrin, total proteins, Magnesium, Calcium, insulin, osteocalcin, hematocrit, hs-CRP, TSH, FT3, FT4. Bone metabolism (Osteocalcin, parathyroid hormone, CTX, Calcitonin), Vitamin D Calcium, Phosphate, Potassium, gastric hormones (GIP, GLP1, GLP2, ghrelin, glucagon, PYY, CCK, leptin, resistin)

Statistical analysis plan:

Student t tests will be used to compare the baseline characteristics of the two groups. Changes between baseline and follow-up will be analyzed by one-way ANOVA followed by Tukey's posttest. A $P < 0.05$ will be considered to be statistically significant by using appropriate software.