

Official title: Impact of Plant-Based Meat Analogues Consumption on Human Health

NCT number: NCT ID not yet assigned

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STUDY PROTOCOL

The study is designed as a postprandial, randomized and crossover intervention trial aimed at comparing the satiation induced by a single intake of grilled vegan “meat” and grilled beef loin at isocaloric and isoproteinic conditions. Participants (25-50 years old), including females and males, will be recruited for the trial and randomly included in a two-stage crossover study. Prior to participation, all participants must express their willingness to participate by signing an informed consent form.

In the first stage, participants will fast for 12 hours, avoiding heavy or late dinners, and refrain from intense physical activity the previous afternoon or evening. They will be randomly assigned to consume either vegan meat (VM) or genuine meat (GM) along with water (100 cL). Under fasting conditions, venous blood samples will be collected via cannula by clinical nurse collaborators and immediately treated with a protease inhibitor cocktail by experienced laboratory technicians.

Consumption of whether VM or GM will be carried out in individual sensory booths at room temperature (22°C). At fixed postprandial times (i.e., 15, 30, 60 and 120 minutes) blood will be collected in K2EDTA Vacutainer® tubes and processed for the analysis of glucose, cytokines, leptin, ghrelin, GLP-1, CCK and insulin concentrations.

During the postprandial period, participants will remain seated and engaged in mild intellectual activities such as reading a book or working on the computer. Any activity that would interfere with the digestion process or influence the postprandial response to the foods under study will be discouraged.

Participants will be specifically asked not to move around, play games or watch movies. After 120 minutes postprandial time, and in order to assess compensatory caloric intake after the first meal, participants will be offered spaghetti Bolognese ad libitum with 100 cL of water until they feel fully and comfortably satiated. Caloric intake will be recorded by measuring the amount of food consumed during this ad libitum meal.

The second stage will take place after a minimum washout period of two weeks following the first stage and will follow the same procedure as described for the first stage, with participants switching meal types. Researchers and technicians involved in the analysis of samples will remain blinded to both the origin of the samples and the identity of the

participants. This information will be securely held by an individual not involved in the study until the completion of the statistical analysis.