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

NCT number: NCT ID not yet assigned

Document data: February 2022

INFORMATION FOR THE PARTICIPANT

Project: "Use of advanced techniques to study sensory perception and physiological response to the intake of vegan products as substitutes for animal-based foods" (VegAnimal)

Participant: **Participant ID:**

Centre: Faculty of Veterinary **Centre ID:**

Researchers: Mario Estévez García and Sonia Ventanas Canillas

PLEASE READ THIS DOCUMENT CAREFULLY AND MAKE SURE YOU UNDERSTAND THE RESEARCH PROJECT. IF YOU AGREE TO PARTICIPATE, SIGN THIS DOCUMENT. BY SIGNING, YOU ACKNOWLEDGE THAT YOU HAVE BEEN INFORMED ABOUT THE PROJECT'S CHARACTERISTICS, REQUIREMENTS, AND RISKS, AND THAT YOU VOLUNTARILY AGREE TO PARTICIPATE. A COPY OF THIS DOCUMENT WILL BE PROVIDED TO YOU.

PURPOSE OF THE STUDY

You have been invited to participate in a research study aimed at understanding "**the effect of consuming red meat and other animal-based foods (milk and dairy products) and commercial meat/dairy analogues on satiety, appetite, hunger, and mood.**"

PROCEDURES AND DURATION

This research includes analyzing the effect of consuming red meat (beef)/milk/ dairy products and their corresponding commercial analogues (i.e., tofu/seitan/plant-based drinks) on satiety, hunger, appetite, and mood through questionnaires and blood biochemical analysis.

The study will be conducted in two phases (with a two-week interval), each lasting approximately 5 hours. During each phase, you will:

Arrive fasting (no food intake 5 hours prior) at the tasting room of the IPROCAR Institute (Avda de las Ciencias s/n), University of Extremadura, Cáceres.

Consume a portion (approx. 400g/400mL) of either beef/milk or its commercial analogue (i.e., tofu or seitan), with mineral water, within 20 minutes.

Complete questionnaires on satiety, appetite, hunger, and mood.

Provide blood samples at fixed times: fasting (before the test), 1.5 hours, 3 hours, and 4.5 hours after food intake.

Blood samples will be used exclusively for non-profit research purposes.

Two weeks later, you will be invited to the second phase, repeating the same procedure but consuming the alternative food (animal-based or analogue, depending on the first phase).

STUDY RESULTS

You may request the overall study results, but not your individual results, which will be treated confidentially in accordance with the Declaration of Helsinki and Spanish Biomedical Research Law 14/2007.

RISKS INHERENT TO THE PARTICIPATION IN THE STUDY

Dietary intervention poses minimal risk, involving commonly consumed foods. Participants will be supervised by medical staff throughout the 5-hour session and may contact them afterward. Blood sampling risks are minimal; sterile, disposable materials will be used, and samples will be collected by qualified nurses.

BENEFITS

There is no financial compensation. However, the study may contribute to understanding how diet affects health. The hypothesis is that meat analogues may influence satiety and mood differently than red meat. This knowledge could inform dietary recommendations, including weight loss.

COSTS

Participation is free of charge. The principal investigators can be contacted at any time at the following phone number: +34 927 257 100 (ext. 51390) or +34 691 774 312, in order to obtain information about the project, and at the following address: Department of Animal Production and Food Science, Faculty of Veterinary, Av. Ciencias, 10003, Cáceres.

Supervising physicians (Drs. Alexis Arjona and Carolina Luna) can also be contacted through the principal investigators.

Refusal to participate will not affect the quality of your medical care.

CONFIDENTIALITY

All data will be treated confidentially. Each participant will be assigned a code to anonymize their data and samples. The principal investigator guarantees that personal data will not be accessible to the research team and that samples will not be used for other studies or transferred to other projects.

Applicable data protection laws will be followed, including:

- Law 41/2002 on patient autonomy and clinical documentation.
- Organic Law 15/1999 on Personal Data Protection.
- Royal Decree 1720/2007.
- Law 14/2007 on Biomedical Research.

If samples need to be stored for future analysis, written consent will be required, as per Law 41/2002.

Study results may be published, but your identity will remain confidential.

PARTICIPANT AND DONOR DECLARATION

I have been informed by the project staff about:

- The advantages and disadvantages of the procedure.
- The purpose of using my samples.
- That my blood samples will be used exclusively for non-profit research.
- That my samples will be anonymized.
- That I may request general information about the use of my samples.
- That I understood the information and had the opportunity to ask questions.

You have the right to participate or withdraw at any time. Refusal will not affect your medical care.

I HAVE RECEIVED A COPY OF THIS DOCUMENT. I AGREE TO PARTICIPATE IN THIS STUDY.

Name: ……
Signature: ……..

Declaration by the medical professional who informed the donor:

Name: ……
Signature:……