University of Guadalajara
Health Sciences University Center
Institute for Translational Nutrigenetics and Nutrigenomics

Effect of coffee and agave inulin-based beverage on appetite sensations, food intake, and ghrelin, GLP-1, and PYY concentrations in adults with obesity

June 2024 – July 2025

INFORMED CONSENT TO PARTICIPATE IN THE TITLED STUDY:

CHEMICAL AND SENSORY CHARACTERIZATION OF A DRINK BASED ON COFFEE AND AGAVE INULIN AND ITS EFFECT ON APPETITE, DIETARY INTAKE, AND BIOCHEMICAL PROFILE IN SUBJECTS WITH OBESITY

Project Manager
Livier Nathaly Torres Castillo, PhD.
Study location:
University Center of Health Sciences of the University of Guadalajara and Bariatric and Metabolic Surgery Unit of the New Civil Hospital of Guadalajara "Dr. Juan I. Menchaca"
Date (dd/mm/yyyy): _____ / _____ / _____
Name of the participant: _____

You are being invited to participate in this research study. Before deciding whether or not to participate, you should know and understand each of the following sections. This process is known as informed consent. Feel free to ask questions about any aspect that will help you clarify your doubts.
Once you have understood the study and if you wish to participate, you will then be asked to sign this consent, of which you will be given a signed and dated copy.

INFORMATION FOR THE PARTICIPANT

JUSTIFICATION OF THE STUDY

In Mexico, almost 4 out of 10 people are overweight or obese, which represents 4 times more than it was 30 years ago. It is for this reason that it has become a necessity to start acting for the well-being of the Mexican population and look for strategies that help people with obesity to comply with nutritional recommendations through foods that are easy to consume and also provide health benefits, as is the case with coffee and agave inulin.
Coffee is one of the most consumed drinks in the world, and Mexicans drink, on average, between 1 and 3 cups a day. Some studies have revealed that coffee has health benefits, such as helping to control blood glucose, reducing tiredness, or preventing certain diseases, mainly mental.
Agave inulin is a type of fiber obtained from a variety of agave native to Mexico, the Agave tequilana Weber. Inulin has been shown to improve food digestion, lower blood cholesterol, and increase the number of beneficial bacteria in our intestines, known as "microbiota."
Although all of these benefits of consuming coffee or agave inulin are already known, their effects on appetite control or weight loss are unclear, and research is needed to clarify them. It is for this reason that, for this study, a drink based on coffee and agave inulin has been designed, which considers the tastes and preferences of the population, with the aim that it can be easily included as part of the usual diet and that In addition, it has few kilocalories, has a high fiber content and provides the necessary amount of compounds that have been shown to have beneficial effects on health and that could have an improvement in appetite control, according to previous research that has been carried out.
Through this study, we aim to know the effect of said drink on appetite, taking care of the quality with which it is carried out so that the information found can serve as support for new

recommendations and strategies that help reduce overweight and obesity in our country, through typical and easy-to-consume foods.

THE PURPOSE OF THE STUDY

You are invited to participate in this research project, which aims to analyze the effect of consuming a drink based on coffee and agave inulin on appetite sensations, dietary intake, and concentrations of ghrelin, GLP-1. and PYY in adults with obesity.

THE PROCEDURE OF THE STUDY

If you decide to participate, you will be scheduled for an initial interview where you will be asked a series of questions to fill out a medical history, similar to when you attend a consultation with a doctor. A questionnaire on eating behavior will also be administered. An anthropometric evaluation will also be performed, including weight, height, waist circumference, fat percentage, body water percentage, and amount of muscle. The last three will be done in electrical bioimpedance equipment, which is similar to a scale, and to get on this equipment, you will have to do so with bare feet (this will not cause any discomfort or pain). A qualified nutritionist will carry out all measurements. Finally, you will be given an appointment to attend your next appointment and asked to refrain from consuming any food containing coffee, caffeine, and inulin for the next 3 days. Then, we will meet with you every week for 6 weeks. At the beginning and end of each session, the following will be done:

- Delivery of drinks for daily consumption at home and a diary to record appetite and food sensations
- Measurement of blood pressure, weight, waist circumference, percentage of body fat and water and amount of muscle
- Blood sample collection
- Capillary glucose measurement
- Answer questionnaires on:

Physical activity, diet, sensations related to appetite, and possible side effects of the drink

- Small tests of 9 foods of different flavors
- Collection of stool samples
- Answer questions you may have regarding the project

This project will give two different types of drinks to compare their effects. The difference is the amount of coffee and agave inulin they contain. For the first 2 weeks of the study, you will consume either drink randomly. The next 2 weeks will be a washout period where you will not consume any of the beverages, and you will also be asked not to consume foods containing coffee, caffeine, and inulin. For the last 2 weeks of the study, you will consume the opposite drink to what you drank in the first two weeks. Once the study period is over, you will be given a personalized meal plan as a thank-you for participating.

-About the storage of samples and clinical and nutritional information for future research projects

Your participation in this study also considers storing your DNA, blood serum and plasma, fecal samples, and all clinical and nutritional information obtained for later research. Your samples will be stored at the Institute of Nutrigenetics and Translational Nutrigenomics (INNUGET) within the University Center for Health Sciences at a temperature of -80 degrees for a maximum period of 8 years or less in case the sample runs out. before. Your samples will be used for subsequent biochemical tests and immunoassays (they measure substances found naturally in the blood), your DNA, and analysis of your microbiota. The information obtained through your samples will be used so that, in subsequent studies, the relationship between those components that are in your blood, your diet, and your DNA can

continue to be known, which will allow more precise health and nutrition recommendations to be given for the Mexican population in the future. The researchers and/or students who participate in this study can access the samples and results obtained at all times. They could also be shared with other Mexican researchers and other countries. Still, at all times, their information and personal data will be protected by a code so that your data and information will have a folio instead of your name or any other identifying information; in this way, we guarantee absolute confidentiality, that is, no one will be able to know that this sample is yours.

Furthermore, so that the researchers can access the information obtained in this study, they will sign a confidentiality letter agreeing to maintain the privacy of the data. The databases are stored on a computer owned by the University of Guadalajara, to which only the main researcher has access. Access to the databases and samples by other researchers and/or students will only be through prior authorization by the main researcher of this project and once the confidentiality letter has been signed, reiterating that the data of Identification of each participant will be separated and it will not be possible to identify who they belong to. You may request a copy of the results obtained from your biological samples, which will be delivered by the main researcher in a sealed envelope. Suppose the information or biological sample cannot be identified. In that case, you will not know what is done with your information or biological sample, nor will you be able to withdraw your consent.

The information obtained here may be published in different scientific journals and conferences in the future, but the confidentiality of your data will always be respected since these will never be made known by any means.

RISKS

Following the Regulations of the General Health Law on Health Research, this research is considered to have a risk greater than minimal because the order in which you will receive the two drinks of this protocol is randomly assigned.

WILLFULNESS

Your participation in this study is completely voluntary, so you can stop participating in this study at any time without having to give any explanation to the researchers.

CONFIDENTIALITY

All information generated and personal data will be treated confidentially. Your identification data will not appear in the databases since only a participant folio will be shown. In the final report of the study, in the publication of results at scientific conferences, in publications in scientific journals, and at all times, your identity will remain anonymous. To guarantee the confidentiality and protection of your data, all forms, questionnaires, and tubes where the blood sample will be taken will only have one page (a number) assigned randomly, and no type of data will appear on them. personnel that could identify you, not even by your date of participation, address, etc.

BENEFITS AND RESULTS

At the end of the session, you will receive free feedback on the interpretation of your weight, height, fat percentage, muscle amount, and body mass index classification. You will also receive nutritional recommendations based on the evaluation of your diet, which will tell you how to improve your eating habits and include highly satiating foods.

CLARIFICATIONS:

• Your decision to participate in the study is completely voluntary.

• You will have no unfavorable consequences if you do not accept the invitation.
• You can withdraw your participation anytime, even if you have already signed this consent without any explanation.
• You may request information obtained during the study, even if it might interfere with your decision to continue participating.
• You will not have to make any expenses during the study.
• Your participation in this project will not affect or modify the care you receive in any services provided by the “Juan I. Menchaca” Civil Hospital of Guadalajara.

CONTACT INFORMATION FOR CLARIFICATIONS OR QUESTIONS

If you have any questions, concerns, comments, or concerns regarding the project, please contact one of the researchers responsible for the project at the addresses below, where we guarantee you will receive a response to whatever your concern may be.

-Livier Nathaly Torres Castillo, PhD
(Cell. 3310585200 ext. 34284) (nathaly.torrescas@academicos.udg.mx)

-Iván Aguilar Vega, LN
(Cell. 3329085516) (ivan.aguilar@alumnos.udg.mx)

-Lisset Citlalic Magaña de la Vega, LN
(Cell. 3318409211) (lisset.magana2305@alumnos.udg.mx)

LETTER OF INFORMED CONSENT

I, _____, declare that I have read and understood the above information and my questions have been answered in simple language, sufficiently clearly and satisfactorily. I have been informed and understand that the data obtained in the study may be published or disseminated for scientific purposes without my name being disclosed. I also understand that at any time and without giving any explanation (if I prefer), I can revoke the consent that I now grant. Therefore, I agree to participate in this research study for the proposed purposes. And I will receive a signed and dated copy of this consent form.

Guadalajara, Jalisco, _____ of the month of _____of the year_____

Witness 1	**Witness 2**
Name and signature	**Name and signature**
Address	**Address**
Relationship with the researcher	**Relationship with the researcher**

This part must be completed by the researcher (or his representative):
I, _____, have explained to the participant the nature and purposes of the research; I have explained to you about the objective of the study and the importance of your participation. I have answered the questions to the best of my ability and finally asked if you had any questions. I accept that I have read and know the corresponding regulations for conducting research with human beings and that I, as well as my work group, adhere to them. Once the question-and-answer session was concluded, this document was signed.

Name and signature of the investigator and/or representative	**Name and signature of the witness**

Relationship with the researcher and/or representative: _____