Effect of Dietary Intervention with a High Intake of Vitamin K on Insulin, Osteocalcin, Leptin, Vitamin K Serum Levels and Cardiovascular Risk in Young Adults with and Without Overweight or Obesity

Protocol ID: CI-04720

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UNIVERSITY OF GUADALAJARA
UNIVERSITY CENTER OF HEALTH SCIENCES
BIOCHEMISTRY RESEARCH LABORATORY
INFORMED CONSENT FORM

Title of the protocol: "Effect of dietary intervention with a high intake of vitamin K on insulin, osteocalcin, leptin, vitamin K serum levels and cardiovascular risk in young adults with and without overweight or obesity."
Sponsor: University of Guadalajara
Research Location: Biochemistry Laboratory of the Department of Molecular Biology and Genomics of the University Center for Health Sciences.
Address: Sierra Mojada #950 Col. Independencia
CP. 44340, Guadalajara, Jalisco.
Tel. (33) 10585200 ext. 33644

Dear Patient,
This is an invitation to participate in a research study that will examine two groups of people: one group of healthy individuals and another group with metabolic disorders such as overweight or obesity. Your participation is entirely voluntary. This study is being conducted with the financial support of the University Center for Health Sciences (CUCS) at the University of Guadalajara (UDG). No pharmaceutical company or other private entity has or will have direct or indirect involvement in this research.
If this document contains unfamiliar words or phrases that you do not understand well, please feel free to ask the staff you are discussing this document with for the meaning of the words or information you do not understand or have doubts about. You should receive a copy of this document to read at home, and if you wish, you can discuss it with your family or friends before participating in this study. No one can force you to participate in this study.
Even if you decide to participate now, you can change your mind later and stop at any time without penalties or loss of benefits to which you are otherwise entitled. Before you sign this consent letter, we will ask if you have read and understood its contents, especially the potential benefits or inconveniences that may result from your participation in this research study.

Summary of the study:

Overweight and obesity are global public health issues, and in Mexico, both are related to increased body weight and fat, which are risk factors for the development of chronic degenerative diseases such as type 2 diabetes mellitus and cardiovascular diseases like hypertension and heart attacks. In Mexico, according to data from the National Health and Nutrition Survey, at the national level, 75.2% of adults are overweight or obese (39.1% overweight and 38.1% obese). A proper diet and a healthy lifestyle are factors that help prevent overweight and obesity. However, the current diet of the Mexican adult

population is not adequate because there is low consumption of recommended food groups, leading to insufficient intake of micronutrients such as vitamin K. Vitamin K aids in blood clotting and bone metabolism by facilitating calcium uptake. The recommended daily vitamin K intake is 120 micrograms for men and 90 micrograms for women. Studies suggest that a high intake of vitamin K has positive effects on insulin sensitivity and reduces cardiovascular risk. Other research has shown that vitamin K supplementation improves insulin sensitivity and glycemic status. However, there is no evidence in our country regarding the effect of a high vitamin K dietary intervention on individuals with metabolic disorders such as overweight and obesity.
The purpose of this study is to assess the effect of a high vitamin K diet on serum vitamin K, insulin, osteocalcin, leptin and cardiovascular risk in young adults who are both healthy and overweight or obese.

Study Design:

This study will include 20 patients in each study group. We will be studying groups of individuals, one group with overweight or obesity, and another group without overweight or obesity according the body mass index (BMI). Both men and women over the age of 20 who meet the research criteria (described below) are eligible to participate. This is an experimental study.

Participant Responsibilities:
If you decide to participate in this study, you will need to follow the following instructions:
• You will need to provide information about your health history and your family's health history.
• You will need to allow for the collection of two blood samples on two occasions, one at the beginning and another at the end of the study, to determine your serum glucose, lipid, vitamin K, insulin, osteocalcin and leptin levels.
• You will need to allow for clinical measurements such as weight, height, waist circumference, hip circumference, and blood pressure to be taken in two occasions, at the beginning and at the end of the dietary intervention.
• You will need to accept and adhere to the recommendations of diet plan given by the nutritionist, to be done for 6 weeks starting from the signing of this document.
• You will need to follow all instructions provided to you while participating in the study (adhering to dietary recommendations and attending all appointments). Failure to do so may result in your removal from the study if you miss two consecutive sessions. If you have any questions, please ask the study coordinator.

Study Procedures:
According to the study plan, you will need to attend a weekly consultation for 6 weeks. In the first and last sessions, we will collect all the previously requested data. From the second session to the fifth session, follow-up consultations and dietary monitoring will be done to resolve any queries regarding the diet.

Risks:
Blood Draw
Drawing blood from a vein can cause local pain, bruising, occasional dizziness, fainting, and very rarely, infection at the blood draw site.

Possible Benefits of Participation:
As a result of participating in this study, you will receive benefits such as personalized nutritional care and you will be evaluated weekly. Your questions will be addressed, and your nutritional health will be monitored on 6 occasions. During these sessions, a comprehensive nutritional assessment will

be conducted, including clinical data such as weight classification, waist and hip circumference, blood pressure, and body fat percentage.
Blood samples will be taken to determine your glucose levels, serum lipid profile (triglycerides, total cholesterol, HDL cholesterol), serum levels of vitamin K, insulin, and osteocalcin. In sessions 1 and 6, these evaluations will take place. In sessions 2, 3, 4, and 5, intermediate assessments will be conducted to address your questions and monitor the diet. Finally, with these results, you will receive proper interpretation so that you can understand your nutritional and metabolic health status on two occasions. Additionally, individual recommendations will be provided based on the observations made by the healthcare professional to help you maintain a healthy lifestyle.
Withdrawal from the Study and Refusal to Participate:
Your participation in this study is entirely voluntary, and you may refuse or discontinue your participation at any time without providing a reason. Withdrawing from the study will not affect your access to any other medical care to which you are already entitled.
Your participation in the study may be terminated by the medical staff for any of the following reasons:
• Requires additional medications that may interfere with the study
• Does not wish to cooperate with the study procedures
• Upon the recommendation of your study doctor

Additional Information Source:

If you have any questions or concerns about your participation or the study itself, you can contact the individuals responsible for this project at any time: Dr. Iris Monserrat Llamas Covarrubias, Dr. Edgar Alfonso Rivera León, or PLN. Lizeth Montserrat Aguilar Vázquez, at the address and phone numbers provided on the first page of this document.

Confidentiality:
The records in which you can be identified and the informed consent, which you have authorized with your signature, will be stored as part of the project's data. These will be used solely for the purpose of the study itself. You will be assigned an alphanumeric consecutive identification code, which will include the initial letters identifying the project and a two-digit number. This code will not be shared with you or with researchers responsible for the study who do not interact with you directly. Your medical history will be kept in the project's records, and only the researchers in charge will have access to it. To ensure the confidentiality of your clinical data, in case you decide to withdraw from the study, your medical history will be destroyed using a paper shredder, and your biological samples will be discarded.
The researchers in charge of the study may be aware of your identity, but they will always respect your privacy. You will not be identified in any way when the results of this study are presented at scientific meetings or in publications. Your identity will not be included in the results of this study to be published in specialized scientific and academic media.

Agreement to Participate in this Study:
• By signing this informed consent form, I declare that:
• I have read and understood the information presented in this document.
• The purpose and procedures related to this study have been explained to me, I have had the opportunity to ask questions, and all my doubts have been resolved.
• I have been informed of the possible risks and benefits of my participation.
• I understand that I am free to withdraw my authorization and discontinue my participation at any time without affecting my health care at the center.

Full Name (participant in the study):

Address:
Signature:
Date:

Full Name of Witness No. 1:
Address:
Signature:
Date:

Full Name of Witness No. 2:
Address:
Signature:
Date:

Name, date, and signature of the person obtaining consent:
Signature:
Date:

DECLARATION OF RIGHTS OF INDIVIDUALS IN EXPERIMENTATION

The rights described below apply to all individuals who are asked to participate in a research study. Therefore, as an individual in experimentation, I have the following rights:
1. To be explained what the study is about and what they are trying to discover. In other words, I must know in detail the objectives of the research.
2. To be told exactly what will happen to me if I participate in a research study.
3. To be informed if any of the procedures, medications, or devices used in the research are different from those used in routine medical practice. If they are different, I must know exactly what the differences consist of.
4. To be accurately and clearly described the frequency and significance of the risks I will be subjected to and the adverse effects or discomforts of the things that will happen to me for research purposes.
5. To be informed if I can expect any benefit from my participation, and if so, what that benefit would be.
6. To be explained other options I have and how these options may be better, the same, or worse than those of this study.
7. To be allowed to ask any questions I may have about the study before giving my consent to participate and during the study (if I decide to participate).
8. To be told what types of treatments are available to me in case of complications.
9. I can refuse to participate altogether, or if I decide to participate, I can change my decision about my participation after the study has started. This decision will not affect my rights to receive medical care that I would receive if I were not in the study.
10. I should receive a copy of the document or written form of my consent to participate in this research.
11. No one can or should pressure me when I am considering whether to participate in the study or not.
If I have any other doubts or questions, I can request that the main researcher or the coinvestigators of this study answer them. Additionally, I can contact the ethics committee of the University of Guadalajara with the committee's chairman at the following address: Sierra Mojada #950 Col. Independencia CP. 44340, Guadalajara, Jalisco. Tel. (33) 10585200.

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Date:
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