“Effect of Propolis or Metformin Administration on Glycemic Control in Patients With Type 2 Diabetes Mellitus”

NCT03416127

April 6, 2017

INFORMED CONSENT FORM

"Effect of Propolis or Metformin Administration on Glycemic Control in Patients With Type 2 Diabetes Mellitus"

The format may contain words or terms that you do not understand; please ask the doctor in charge of the study in your interview to explain in case this situation exists. Sign this informed consent form until all your doubts are satisfactorily clarified, and you are convinced that you want to participate in the study.

Purpose of the study

The purpose of the study is to evaluate the effect of the administration of propolis or metformin on glycemic control in patients with Type 2 Diabetes Mellitus without drug treatment, this due to the continuous growth in the incidence and prevalence rates of Diabetes, where glycemic control is by nature the protagonist of unleashing it. Currently, the first-line drug treatment in newly diagnosed patients is metformin, and although its effect to reduce hyperglycemia is well documented, both in monotherapy and in combination, there is a marked tendency to develop a progressive deterioration in glycemic control and abandonment of treatment, however, recent studies have shown that natural products play an important role as alternatives in the treatment of various diseases, mainly due to their low toxicity. Such is the case of propolis, a balsamic resinous material collected from shoots, exudates of trees and other parts of plants by the bee *Apis mellifera*, of which various studies in animal models and clinical trials have shown that it could be considered as an agent antidiabetic.

The study will last 12 weeks, which includes 6 visits and the participation of 36 people who will receive:

1) Metformin, an antidiabetic medicine. It will be taken 2 times a day, 1 capsule per dose, 1 at breakfast and 1 at dinner, provided free of charge and in sufficient quantity during the three months of the study.

2) Propolis, which is a capsule that when consumed has shown effects on Type 2 Diabetes Mellitus. It will be taken 2 times a day, in 1 capsule per dose, 1 at breakfast and 1 at dinner, being provided free of charge and in sufficient quantity during the three months of the study.

3) Placebo that looks and looks like medicine but is not and therefore will have no effect on your weight, fat, blood glucose or blood pressure. The placebo is administered so that neither you nor the doctor evaluating the study know what medication you are taking, however, this information can be obtained if required.

So we think you could be a good candidate to participate in this project. You and the rest of the study participants will take the treatment as directed and you will not know which group you will belong to.

Procedures

If you agree to participate, the following will take place:

1. **Procedures that are routine in the care of patients in this service:**

You will come here with us on a fast from at least 8 hours to 8:00 AM.

a. *Clinical Procedures:* You will have a medical history that includes a complete physical exam with the measurement of your blood pressure, weight, height and waist.
b. *Laboratory procedures:* we will take a venous blood sample (approximately 2 teaspoons of your blood), from one of your arms to perform some laboratory studies, then you will be given a drink containing 75 grams of glucose diluted in 300 ml of water, to measure your blood glucose after an oral glucose load and thus determine if you are intolerant to it. In addition, the laboratory studies that we will perform include the measurement of your fasting glucose level, creatinine, glycated hemoglobin A1c and a lipid profile. For your safety and hygiene, all the material used in this study is sterile and disposable, and at the end of the planned analyzes, the rest of the sample will be destroyed.

The purpose of conducting clinical and laboratory studies is to learn more about your general health conditions and glucose levels both fasting and 2 hours after a 75g glucose load. It will take us approximately 2 hours to perform these clinical and laboratory tests. We will give you the results of your lab studies within 3 days.

Once this letter of consent has been signed and if the criteria to enter the study are met, another day of fasting of at least 8 hours will be scheduled at 8:00 AM where the following specific procedures will be performed:

2. Specific procedures for this investigation:

a. Nutrition counseling will be provided by trained staff.
b. Laboratory tests will be taken at the first visit and at the end of the study to compare the glucose and hemoglobin A1c levels you had on admission with those you had on your exit from the study.
c. The visits with us will be monthly, and within them, we will take your height, weight, waist circumference and blood pressure to observe the evolution you have had with the medicine. You will also be asked if the capsules have been taken every day, if there has been a lack of taking at any time, as well as the possible adverse effects with the treatment.
d. After 3 months of administration of the assigned drug, you will be cited again with a fast of at least 8 h at 8:00 AM and the clinical measurements will be taken at the beginning of the intervention. In addition to the possible adverse effects and adherence to treatment.

The knowledge that results from this research will help to know and improve the treatment schemes for patients with Type 2 Diabetes Mellitus, in this case, it will allow the medical community to recommend the use of propolis not only to lower blood glucose but also to decrease the components of the disease already mentioned above.

Possible risks and annoyances

Discomforts or risks associated with clinical evaluation procedures: measurement of weight, height, blood pressure, waist, and heart rate are non-invasive clinical measurements that do not cause pain, discomfort, or risk.

Discomforts or risks associated with laboratory procedures: discomfort during blood sampling is minimal. On some occasions, the procedure for taking a blood sample may cause mild pain or slight discomfort, it is possible that a bruise may form. Although there is no clinical evidence of adverse effects to treatment with propolis, it can cause mild intestinal problems if you are allergic to bees or any product made from the components of bees. In the case of metformin, it is also associated with gastrointestinal intolerance.

Possible benefits you will receive from participating in the study

You will not receive payment for your participation in this study, nor does it incur any expense to you. The treatment that you will be given is aimed at improving your blood glucose levels and your weight, however, it is not a guarantee of an optimal drug result. Although the direct benefits for you may not exist, the results of this study will contribute to the advancement of knowledge about the beneficial effects of this treatment in patients with type 2 Diabetes Mellitus, and the results will be relevant for the better management of people like you. Considering the above, you will be provided with the results and a clinical summary of what was done in the study, so that your family doctor can use it to modify and monitor your treatment. Your participation in this study is completely voluntary. For the purposes of this research, we will only use the information that you have provided us from the time you agreed to participate until the time you let us know that you no longer wish to participate.

Privacy and confidentiality

The information that you provide us that could be used to identify you (such as your name, telephone number, and address), the responses to the questionnaires, and the results of your clinical tests will be kept confidential to guarantee your privacy.

The team of researchers, people involved in your health care, and your regular doctor will know that you are a participant in this study. However, no one else will have access to the information you provide to us during your participation in this study, unless you choose to do so. We will provide your data only if it is necessary to protect your rights or well-being (for example, if you suffer physical harm or need emergency care), or if required by law.

When the results of this study are published or presented at conferences, for example, no information that could reveal your identity will be released. Your identity will be protected and hidden. To protect your identity, we will assign you a password that we will use to identify your data, and we will use that password instead of your name in our electronic databases.

Financing

The financing will be with own resources of the University of Guadalajara.

Declaration of informed consent

By signing this consent, I acknowledge that I have been informed about the methods and routes of administration of study drugs, the procedures, and tests to which I will be subjected, and the inconveniences, benefits, and inconveniences that may arise. I certify that I have read (or someone has read to me) the content of this consent form. I have had sufficient time to understand that all technical language used in the description of this research study has been satisfactorily explained to me. I received an adequate and understandable answer to all my questions that I have received a copy of this document, which I will keep in safe custody for future consultations. I'm free to withdraw from the study at any time without losing any benefit or suffer any penalty. I give my consent to be included in this study.

Participant name: _____

Participant signature: _____

Participant's address: _____

Phone: _____ Date: _____ / _____ / ____

Witnesses

Name: _____

Relationship: _____Signature: _____

Address: _____ Date:_____ / _____ / _____

Name: _____

Relationship: _____Signature: _____

Address: _____ Date:_____ / _____ / _____

Investigator statement

I have explained the nature and purpose of this study to you and the possible risks and benefits of your participation. I have cleared all your doubts by answering all your questions. I believe that you understand the information described in this document and freely consent to participate in this research study.

_____ _____

Investigator's name and signature Date