“Effects of dapagliflozin on blood pressure variability in patients with prediabetes and prehypertension without pharmacological treatment: a randomized”

NCT03006471

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INFORMED CONSENT FORM

"Effects of dapagliflozin on blood pressure variability in patients with prediabetes and prehypertension without pharmacological treatment: a randomized"

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

Prediabetes and prehypertension are conditions that have a high risk of developing type 2 diabetes mellitus and hypertension respectively and are considered a major health problem in the world. Early detection and control of high blood pressure and high blood glucose levels prevent heart disease to a large extent.

The purpose of this study is to evaluate your general health conditions, detect, monitor, control or lower glucose levels and blood pressure. Our study is focused on measuring your blood glucose as well as your blood pressure with an instrument called ambulatory blood pressure monitoring, also called ABPM during a period of 24 hours with the administration of dapagliflozin or placebo in patients with prediabetes and prehypertension without drug treatment.

Study description

30 patients participated in this study; 2 groups (15 patients per group) randomized to one of the following treatments:

- Dapagliflozin: it is a drug used to treat patients with type 2 diabetes mellitus, it acts at the renal level; causes the elimination of glucose, water and salt in the urine, in this way the levels of glucose in the blood decrease as well as the blood pressure.
- Placebo: it is the same shape, size and color as dapagliphozin, it looks like a medicine but it is not; therefore, it will not have any effect on your body, much less on your blood pressure.

During this study; your doctor in charge, nor you, will know which group you belong to, nor will they know who takes dapagliflozin or placebo (only a person outside the research will know), or on the contrary that some circumstance requires it.

Both medications will be provided free of charge, with a sufficient quantity and with instructions on how to take it.

The study will be 3 months, with 8 visits:

■ Visita 1 (Día -7 a -2):

All possible candidates will be summoned at 08:00 am with a 12 hour fast. In this first visit, information regarding the study is provided; the objectives, characteristics, procedures, as well as its potential benefits and risks. If the individual accepts and the investigator in charge decides that the patient meets the clinical criteria for participation in the study, the informed consent will be signed.

A medical history will be taken, anthropometric measurements and vital signs (weight, height, BMI and office BP) will be taken. A blood sample (5 ml of blood) will be taken to measure fasting plasma glucose and hemoglobin glycated A1c fraction.

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 approximate time is 30 minutes.

■ Visit 2 (Day -1):

Laboratory results are assessed and it is confirmed that the individual meets all the clinical and laboratory inclusion criteria, if so, ABPM will be placed for 24 hours at 8 am ± 2-h-

■ Visit 3 (Day 0)

24 hours after the placement of the ABPM, the patient is scheduled for removal. Their treatment is randomized by another investigator outside the present study, either in the dapagliflozin group or in the placebo group.

A diary will be given to the patient where the daily dosage is described, in addition the medication corresponding to the first month of the intervention will be delivered and finally general nutrition recommendations will be given since during the study it is not indicated to start some type of diet to lose weight. Weight or an increase in physical activity. The control patient will be given an appointment 30 and 60 days respectively after starting treatment.

■ Visit 4 and 5 (Days 30.60 ± 2 respectively)

During the first and second months of the intervention, you will be summoned to monitor adherence and tolerability to the treatment through the diary, clinical measurements and capillary blood glucose, vital signs will be taken and the medication corresponding to the current month will be provided.

■ Visit 6 (Day 90 ± 2)

After 90 days at the beginning of the intervention, the individual will be summoned again and the clinical and laboratory measurements will be taken in the same way as they will be done in the baseline visit, with a 12-hour fast, the ABPM will be placed for 24 hrs.

■ Visit 7 (Day 91 ± 2)

24 hrs after placement of the ABPM, the patient is scheduled for removal at 8 am ± 2-h.

■ Visit 8 (Day 120 ± 2)

Within the first 4 weeks, the patient will be summoned to deliver the final results and their evolution during the intervention will be explained. Finally, you will be given medical-nutritional recommendations to continue treatment if the patient requires it.

The present study was consistent with the Helsinki declaration and was approved by the Local Committee of Ethics and Research of the University with this register number CEI/357/2016. This informed consent will be obtained from the participants before performing any intervention or evaluation. The principal investigator explained to each participant the nature, risks and benefits of the study.

New information

During the course of this study, we will inform you of any findings and in the event of new interventions we will again request your written consent.

Risks of the intervention

During the collection of blood samples, one or more punctures (taking blood with a needle and syringe) will be required in any of the veins in your arms, during which you may feel pain and occasionally a bruise may form. In the area where the blood is taken.

In order to avoid unnecessary risks for you and your family, the medicine that is given or strictly prescribed should be consumed only by you and in the way that is indicated.

You could have: back pain, dizziness, increased urinary frequency, pain when urinating, genital and urinary tract infections, changes in kidney function (creatinine), these discomforts occur rarely, as it will depend on each patient. It is essential that you inform the treating doctor in this investigation of all the discomfort you may suffer throughout the study since your treating doctor knows the best way to treat them, which may include stopping treatment.

Benefits of the intervention

You will not receive payment for your participation in this study, nor does this study imply any expense for you, instead you will benefit from a medical evaluation, clinical and laboratory measurements. At the end of the study, you will be given professional and multidisciplinary medical and nutrition guidance if necessary.

Hospital visits, procedures and medication will be at no cost to you if necessary during our intervention.

Although the direct benefits for you may not exist, the results of this study will contribute to the advancement of scientific knowledge for new applications with the use of dapagliflozin, as well as for the management of people who, like you, have the same problem.

Participation or withdrawal from the study

Your participation in our study is completely voluntary. You can decide not to enter or discontinue your participation, with a prior visit with your treating doctor, as well as he may suspend your participation without your consent if you need additional treatment, do not follow the instructions or there is suspicion that the medicine is harmful to your health. However, you will still have the benefit of medical care and follow-up.

Privacy and confidentiality

The information provided to us will be confidential to guarantee your privacy, including the presentation of the results at congresses or conferences, unless your health is at risk and / or you so wish.

Financing

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

Declaration of informed consent

What this study consists of has been clearly explained to us; the methods, procedures, administration of the drug, as well as the benefits and adverse effects that may occur. I have also read and / or someone has read to me the content of this consent. We have been given the opportunity to ask questions and they have been answered in plain language and there has been no doubt, and I have been provided with a copy of this form.

I understand that we are free to withdraw from the study at any time with prior notice to the researchers of our reasons, without losing benefits or obtaining any penalty. We freely and without reservation give our consent to participate as a patient in this study.

Date: _____ / _____ / _____

Participant name: _____

Participant Signature: _____

Participant´s address: _____

Phones:_____

Witness 1 **Date: _____ / _____ / _____**

Name: _____Relationship to patient:_____

Signature: _____
Address: _____

Witness 1 **Date: _____ / _____ / _____**
Name: _____Relationship to patient:_____
Signature: _____
Address: _____

Investigator Statement **Date: _____ / _____ / _____**

Manager's name and signature:_____