ID: R-2016-785-094

Effectiveness of the Treatment With Dapagliflozin and Metformin Compared to Metformin Monotherapy for Weight Loss on Diabetic and Prediabetic Patients With Obesity Class III

NCT03968224

Approval date: 11-Nov-2016

Informed consent letter

LETTER OF INFORMED CONSENT TO PARTICIPATE IN INVESTIGATION PROJECTS

PROJECT TITLE: **"**Effectiveness of the treatment with dapagliflozin and metformin compared to metformin monotherapy for weight loss and its effects on waist circumference, triacylglycerol concentration and blood pressure on diabetic and prediabetic patients with obesity class III. Open, randomized clinical trial**".**

DATE AND PLACE: Mexico City, Mexico
Approval date 11-Nov-2016
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You are being invited to participate in this study because you have a disease called obesity. You must read this letter before you decide if you want to participate in this study. This letter may include words that you could find difficult to understand, in that case please ask the medical personal to explain anything you find confusing.

JUSTIFICATION AND OBJECTIVE OF THE STUDY (as will be presented to patients in non-technic language).
Obesity class III is defined as a body mass index above 40 kg/m^2. This measure is obtained by dividing the current weight on your height and again about your height. This disease increases the risk of other conditions that affect your heart as prediabetes (fasting sugar level above 100 mg/dl and less than 126 mg/dl or greater than 140 mg/dl after giving sugar) or diabetes (fasting blood sugar level greater than 126 mg/dl or greater than 200 mg/dl after giving sugar), high blood pressure and elevated blood lipids.

You have been admitted to the Obesity Clinic to underwent surgery for weight loss. As part of the follow-up, you will receive recommendations for diet and exercise according to your current weight and doctors will monitor diseases present at this time. Surgery should drop up to 10% of the extra weight, which is calculated with the weight that you should have according your height.

We have detected elevations in your glucose (prediabetes or diabetes), so you will receive treatment with metformin as recommended for initial treatment. There are other medications as dapagliflozin that added to metformin may help to lower your glucose, lose weight, waist (belly fat), triglyceride (lipids) and improve your blood pressure. This drug is NOT a drug provided at the IMSS and there is no previous studies on how much it lowers these measures in patients with obesity. The aim of the study is to determine what is the difference in these measures between patients randomized to a treatment with dapagliflozin combined with metformin and those taking metformin alone.

PROCEDURE
If you accept and sign your inclusion to this study you must answer some questions related to your diseases (clinical history). After that, we will take you some routine labs equivalent to 10 ml of blood. First labs will be took a week after your first date at clinic and after months: 1, 3, 6 and

12. If you are admitted to bariatric surgery before this time, data will be registered until that time. In each date at Obesity Clinic, your labs will be registered as well as your weight and waist circumference (measurement of your belly).

During the first date at clinic your treatment for sugar control will be provided. You might receive dapagliflozin and metformin combination or only metformin. In later dates you must bring your containers (even if you don't finish your treatment) and then next treatment will be provided. If you have some symptoms during the treatment, you may go to emergency room for medical assistance and then we will decide of you may continue with your treatment.

POSSIBLE RISKS AND BOTHERSOME EFFECTS
Bothersome effects will be minimal during blood collection: pain during sampling or a discrete bleeding that disappear after a week. During glucose oral test you may have nausea or vomiting. If you vomit during study, we must repeat it.

POSSIBLE BENEFITS
You will not be directly benefited from your participation in this study. You will not receive any kind of compensation or money gratification. However, if you decide to participate the information generated will be useful for treat other patients with obesity.

PARTICIPATION OR WITHDRAWAL
You have a complete guarantee to receive answer to any doubt generated by your participation in this protocol and you are also free to withdraw your consent at any time or leave the study without this affecting the medical attention you receive in this Institute.

PRIVACY AND CONFIDENTIALITY: all the data gathered will be kept under a code number without any possibility of being identified by any unauthorized personnel. Your name and data will not appear in any publications resulting from this study.

BENEFITS AT THE END OF THE STUDY: Patients will not receive any benefit at the end of their participation.

In case there is any doubt or comments, you will be able to address them directly to the Principal Investigator in charge of this study: **Dr. Aldo Ferreira Hermosillo, M.Sc,** Endocrinology department, Hospital de Especialidades Centro Médico Nacional Siglo XXI, IMSS. E-mail: aldo.nagisa@gmail.com. Telephone number 56276900 ext 21551

In case of doubts or comments about your rights as a participant in a protocol study you can address them to the Ethic Committee in Investigation CNIC, IMSS. Cuauhtémoc 330 4th floor Block “B” Convention Center, Col. Doctores. México, DF. Zip code 06720 Telephone (55) 56276900 Extension 21230. E-mail: comité.eticainv@imss.gob.mx

I hereby accept that I have been informed of the purpose of the study, that I have been given enough time to read the letter of informed consent and that my questions have been answered

to my satisfaction. Therefore, my signature implies my desire to participate in this study by my own decision.

Name and signature of the patient	Name and signature of the person requesting consent
Name and signature of the witness No 1	Name and signature of the witness No 2