NATIONAL POLYTECHNIC INSTITUTE

School of Medicine

SECTION OF GRADUATE STUDIES AND RESEARCH

"Gene modulation of NLRP3, IL-1β and TNF-α in peripheral blood of patients with exogenous obesity treated with Berberine."

Principal Clinical Research

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NATIONAL POLYTECHNIC INSTITUTE

School of Medicine

Postgraduate Studies and Research Section

Obesity Projects

Informed Consent to participate in a Research Study with human subjects.

Mexico City, Mexico, at _____, 20__.

Protocol Title: Gene modulation of NLRP3, IL-1β and TNFα in peripheral blood of patients with exogenous obesity treated with Berberine.

Place of accomplishment: Superior School of Medicine of the National Polytechnic Institute around Obesity Projects belonging to the section of postgraduate studies and research.

Principal Investigator; Dr. Modesto Gómez López

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Legal basis for this informed consent: This research complies with the ethical principles of the General Law of Health and the Regulations of the General Law of Health on Research for Health, as referred to in Chapter I. Common provisions, Articles 13 and 14. In all research in which the human being is the subject of study, the criterion of respect for his/her dignity and the protection of his/her rights and well-being must prevail. In this research it was considered with minimum risk according to Article 17 and in compliance with the following aspects mentioned in Article 21.

Before agreeing to participate in this research study, it is important that you read and understand the objective, procedures, benefits, risks, as well as your right to withdraw from the study at any time. This document is called informed consent, please take the time to read it and discuss it with your doctor, family or friends. If you do not understand some of the terms, ask questions until everything is clear. At the end you will be asked to sign this document if you agree to participate in the study and a copy will be provided to you.

Justification for the study

Obesity is a health problem in which Mexico occupies the first places, in addition to the fact that obesity is the trigger for other diseases. We consider it is important to continue researching on this disease, to control or reduce its complications; because in our population it continues to increase with serious affectations to their health and their lifestyle lacks quality day by day. It is of interest to identify molecular markers or key molecules to develop new strategies to address this disease.

Aim of the study

You are being invited to participate in a research study aimed at determining the Gene Modulation of NLRP3, IL-1β and TNFα in peripheral blood of patients with exogenous obesity treated with berberine.

Study Procedures

The study will last 6 months in total, patients with exogenous obesity, which is defined as an abnormal accumulation of fat that may be detrimental to health, will participate in this study. To determine the degree of obesity, the body mass index (BMI) is used, which is calculated by dividing a person's weight in kilos by the square of their height in meters (kg/m2) and that value gives us >30kg/m2, indicating that the patient has obesity and can participate in addition to meeting the criteria such as being 18 to 60 years old. After the evaluation it will be determined if you meet the section criteria to be able to participate in the study. You will be randomly assigned to a group which may be:

Group I. You will be given a nutritional plan according to your caloric requirements for lifestyle change and you will be scheduled biweekly for 3 months to assess your weight, height, body mass index and percentages of fat or muscle.

Group 2. You will be given a nutritional plan and controlled moderate aerobic exercise that will consist of a goal of 10,000 steps or 150 minutes per week. The patient will be given a lifestyle change plan in accordance with their nutritional requirements.

Group 3. You will be given a nutritional plan, moderate aerobic exercise with a goal of 10,000 steps or 150 min per week; and the phytopharmaceutical Berberine will be taken 3 tablets every 8 hours for 3 months.

Group 4: You will only go for a medical check-up to evaluate your weight, height, fat percentage, visceral fat.

Biweekly sessions will be carried out for 3 months, then monthly for 6 months, for a medical check-up to evaluate your weight, height, fat percentage, visceral fat.

Blood samples will be taken at the beginning of the study, that is, after informed consent, at 3 months, and assess the expression of some genes related to obesity and inflammation, the blood samples are for 4 ml in every occasions.

- To go to the sample collection, an appointment will be made at 7 am, with fasting of at least 8 hours, the sample will be collected in Vacutainer tubes (BD, USA).

- The anthropometric evaluation will determine weight, height, body fat percentage, visceral fat percentage.

Nutritional Plan will be a "classic" hypocaloric diet: Recommended in most guidelines and consensus, it establishes a deficit of 500 to 1,000 calories per day, and a balanced distribution of nutrients: 45-55% carbohydrates, 15-25% proteins, 25-35% total fats and 20-40 g of fiber 1. The number of mealtimes will be distributed in 5: 3 main meals (breakfast, lunch and dinner) and two additional snacks (morning and evening).

You agree to attend your consultations and laboratory test in a timely manner, and you will be explained the conditions in which you must come for the day of the blood sample collection. In the last visit you will receive the results, and you will be able to know everything about your health.

Benefits of the study

The benefit of your participation in this study is that you will know clearly your current health status, you will receive clinical data, anthropometric studies, nutritional orientation and clinical care to guide you to reduce the risk of obesity-related diseases. The laboratory tests are free of charge for you and the results obtained will be provided to the physicians who will follow up with you during your participation in the study. This study will allow other patients in the future to benefit from the knowledge gained from the results and analysis.

Risks associated with the study

During the procedure to obtain the blood sample from the vein in your arm, you may occasionally feel some discomfort or slight pain. Some people may experience a hematoma (bruise) that will disappear in a few days.

If you should experience any adverse event related to the blood sample collection, you should go to the School of Medicine Medical Service area to obtain appropriate medical attention and please contact Dr. in C. Eleazar Lara Padilla, telephone 044-55-13-38-39-55.

Confidentiality and Privacy

Personal information, information obtained by questionnaire and laboratory results are coded so that your name will not appear in any information or publication generated by the study. All information will be stored in a secure location in accordance with internal procedures and government regulations to protect personal and laboratory information, and records of your participation in the study will be kept confidential. However, the investigators and under certain circumstances the Health Authorities of the Secretary of Health, the Research Ethics Committee, will have access to the information.

Compensation

You will not have to pay any expenses during the study

You will not receive payment for your participation

Pertinent clarifications

Your decision to participate in the study is completely voluntary.

In the study, your constitutional, human, patient, sexual and reproductive rights will not be violated in any way.

There will be no adverse consequences for you in terms of the quality, warmth and safety of the care you deserve if you do not accept the invitation or withdraw from the study.

If you decide to participate in the study you can withdraw at any time you wish, even if the investigator responsible does not request it, and you can inform or not, the reasons for your decision, which will be respected in its entirety, to revoke your participation in the study it will be enough to verbally inform the investigator.

During the study or at the end of it, you may request that a copy of all the information that has been collected about you because of your participation in this study be given to you.

You may also submit your complaints and disagreements with the investigators' actions to the investigators: Dr. Modesto Gómez López cellular 044-55-19-32-95-03 and Dr. Eleazar Lara Padilla cellular 044-55-13-38-39-55 or to the Research Ethics Committee (IRB) at 57296000 extension 62804.

If you consider that there are no doubts or questions about your participation, you may, if you wish, sign this Letter of Informed Consent.

Informed Consent

I:_____ have read and understand the above information and my questions have been fully, clearly and satisfactorily answered. I HAVE been informed and understand that the data obtained in the study may be published or disseminated for scientific purposes.

I agree that the information, diagnostic, therapeutic tests and/or biological samples/tissues collected will be obtained for this and other studies, in addition to the preservation of biological samples and tissues obtained for future research purposes, in which case I understand that the preservation procedure will be the direct responsibility of the principal investigator.

If you require more information about the study, if you have any doubts, you can contact the principal investigator Dr. Modesto Gómez López cellular 5519329503, email moygl@yahoo.com, the associate investigator Dr. Eleazar Lara Padilla cellular 044-55-13-38-39-55, email elarap@ipn.mx and Dra Nadia Mabel Pérez Vielma, cellular 5520583053, email nadiampv@gmail.com, this letter of informed consent has been duplicated and one of the originals will be given to the volunteer participating in the study.

Signature of acceptance of the commitments derived from this document:

_____

Full name and signature of the participant

_____

Full name and signature of witness 1

_____

Full name and signature of witness 2

_____

Full nameand signature of researcher