NATIONAL POLYTECHNIC INSTITUTE
SUPERIOR SCHOOL OF MEDICINE
DIVISION OF POSTGRADUATE STUDIES

LETTER OF INFORMED CONSENT TO PARTICIPATE IN RESEARCH PROTOCOLS

Name of study: Effect of hyperbaric oxygen therapy on oxidative stress and inflammation in patients with diabetic foot ulcers.

Place and date: _____
Registration number:CE-CIS-038, Mexico, CDMX, December 28th, 2018

Justification and objective of the study:
This study seeks to assess changes in genes that are related to inflammation and oxidative stress in patients with type 2 Diabetes with diabetic foot treated with hyperbaric chamber, the objective is: To evaluate changes in gene expression in inflammation and oxidative stress in patients with diabetic foot treated with hyperbaric oxygen.

Procedures:

It is important to mention that to participate in this study you must be a patient with type 2 diabetes mellitus and diabetic foot attended at the Clinic to treat patients with diabetic foot of the Secretary of Health, of the CDMX. It is important that you read in detail the following information which consists of the procedures of the study, its risks and benefits, in case you wish to participate you must sign this letter of informed consent and you will be informed of the dates and places for the beginning of the procedure.

1. You will schedule an appointment with a Family Physician who will take a medical history.
2. You will be given a medical appointment for laboratory studies with the taking of 3 tubes (14ml which is equivalent to a tablespoon); 1 tube without anticoagulant of 6 ml to determine the value of glucose, uric acid, cholesterol, triglycerides, urea and creatinine in blood; a second tube of 4 ml with EDTA for determination of glycosylated hemoglobin (a study that measures the average of sugar in the last three months). A third tube of 4 ml with EDTA for the determination of the expression of genes related to inflammation and oxidative stress. If you present any severe alteration in your laboratory results you will receive medical attention from your physician.
3. You will attend 32 sessions with hyperbaric chamber for 60 minutes, one daily from Monday to Friday with breaks on Saturday and Sunday.
4. Every week you will be evaluated by a physician to assess the evolution of the foot and adjust the medical treatment.
5. In the 12th session a second sample of 4ml will be taken in a tube with EDTA to perform a new determination of the expression of genes related to inflammation and oxidative stress.
6. At the end of the 30 sessions you will be reevaluated and a third sample of 4 ml will be taken in a tube with EDTA to perform a new determination of the expression of genes related to inflammation and oxidative stress.
7. Finally, a medical appointment will be made for laboratory review, to know and termination of the study.

Possible risks and discomfort:

The present study has a risk greater than the minimum sustained based on art. 17 and 17 bis of the General Health Law where health risks are evaluated, this risk is due to the fact that during the study needles will be used for the extraction of blood for laboratory studies, a common procedure in her medical treatment,

All the activities described will be carried out by medical personnel with experience in each area. If you should experience any discomfort or have any doubts, you will be attended by the personnel in charge of the study.

Possible benefits you will receive by participating in the study:

The present study will be able to provide clinical and scientific information on how to train patients in a better way to help them know in detail the effect of hyperbaric chamber treatment in patients with diabetic foot.

Information on results and treatment alternatives

At the end of the study, you will be informed personally and confidentially of the results, so that you will know which intervention was the easiest to understand and provided the most information.

Participation or withdrawal

Your participation will be voluntary, therefore, in spite of having signed the present letter of informed consent, you will be able to do so at the moment you decide not to continue, without interfering with the care you receive in your corresponding family medicine unit.

In case of collection of biological material:

I do not authorize the sample to be taken.
I do authorize the sample to be taken for this study only (samples will be stored for one year and then discarded).

Benefits at the end of the study:

The information gathered will allow us to learn new educational techniques to support other patients with type 2 diabetes.

In case of doubts or clarifications all will be answered and clarified by the doctors participating in the study, being the main responsible Dr. Modesto Gómez López with telephone 5519329503 with address at the Escuela Superior de Medicina, of the Instituto Politécnico Nacional in the laboratory of molecular biology in the inflammatory process in the Postgraduate building with address in Plan de San Luis y Díaz Mirón s/n, Col. Casco de Santo Tomas, Alcaldía Miguel Hidalgo, C.P. 11340, Mexico City.

In case of doubts or clarifications about your rights as a participant, you may contact: Comisión de Ética de Investigación de la Escuela Superior de Medicina, del Instituto Politécnico Nacional, located at Plan de San Luis y Díaz Mirón s/n, Col. Casco de Santo Tomas, Alcaldía Miguel Hidalgo, C.P. 11340, Mexico City.

_____	_____
subject's name and signature	Name and signature of person obtaining consent
Witness 1	Witness 2
_____	_____
Name, address, relationship and signature	Name, address, relationship and signature