WRITTEN INFORMED CONSENT FORM

Research project: "NEW DIAGNOSTIC SYSTEM FOR THE EARLY DETECTION OF CHRONIC RENAL DAMAGE ASSOCIATED TO TOBACCO CONSUMPTION: PREVENTIVE AND PERSONALIZED APPLICATION ".

Study summary

Tobacco causes kidney damage that can degenerate into long-term chronic kidney failure. However, the parameters usually used in the clinic are not useful to detect it. Therefore, our first objective would be to detect subclinical kidney damage in smokers using a battery of early markers (NAG, KIM-1, NGAL, PAI-1, etc). For this purpose, a cross-sectional study with different groups of patients from a Primary Care Center is proposed. Through these markers, the influence of tobacco on kidney damage, in patients with and without risk factors associated with it, will be evaluated. On the other hand, based on previous studies of our group, we think that tobacco may predispose to suffer renal damage when smokers are exposed to other potentially nephrotoxic events (pharmacological treatments, diagnostic tests ...). Thus, our second objective would be to study if certain predisposition markers are capable of detecting, among those who smoke, those who are predisposed to suffer renal damage. This objective will be carried out through a prospective longitudinal study with patients recruited in the previous objective. Finally (objective 3), we will study (prospective longitudinal study), whether smoking cessation reduces subclinical renal damage and / or predisposition to kidney damage. To do this, patients from a Smoking Unit will be recruited. In short, this project addresses two issues of high concern in the health field, smoking and chronic kidney disease.

Study subjects

The study will not alter at all the standard procedure to follow with patients. There is no risk for the people included in the study, as no invasive procedures will be performed, except for a blood draw at the baseline visit.

It is a prospective study with the following inclusion and exclusion criteria:

Inclusion criteria:

Patients of legal age who agree to participate in the study and do not meet any of the exclusion criteria.

Exclusion criteria

Patients who are terminally ill; presenting previously diagnosed renal failure; that during the week prior to the sample collection, or at the time of the sample, they have been treated with potentially nephrotoxic drugs; Patients who do not wish to sign the informed consent.

Obtanment, collection and processing of urine samples

Objective 1- a single urine sample will be obtained at the time of inclusion in the study.

Objective 2- urine samples will be obtained at 12 and 24 months after inclusión in the study.

Objective 3- urine samples will be obtained at the time of inclusion in the study, (inclusion in the smoking cessation program) and at 3, 6 and 12 months.

All the samples will be collected in the health centers and will be transferred to the "Complejo Asistencial Universitario de Salamanca (CAUSA)" Samples Bank, where they will be handled and conserved. Once in the Biobank, they will be frozen in several aliquots at -80º C until they are used.

The Main Research of the project, will be the person responsible for the samples, which will be available to be used in future research studies provided that the assignment for the Research Projects for which they are requested has been previously approved by the Biobank Research and Ethics Committees.

Study code:

I, ...
(name and surname)

I have read the information sheet that has been given to me.

I was able to ask questions about the study.

I have received enough information about the study.

I have spoken with Dr.....
(researcher's name)

Comprendo que mi participación es voluntaria.

I understand that I can withdraw from the study:

1.º When I want.

2.º Without having to explain.

3.º Without this having an impact on my medical care.

I freely give my consent to participate in the study, and I authorize the clinical data obtained in the course of this study to be:

1.-Registered and used in accordance with the criteria explained in the information sheet.

2.-They can be presented to the promoter of the study for its scientific analysis, and to the competent authorities for its verification, as long as it is ensured that my identity can not be related to my data (dissociated data).

3.-They are inspected as personal data by representatives authorized by the Promoter as well as by national and international health authorities; all in order to verify the data and the correct conduct of the study.

I agree that the urine samples obtained for the study can be used in the future for new analyzes related to the disease or study drugs not provided for in the current protocol:

YES ☐ NO ☐

Date (*) Participant signature

I have commented on this clinical research study with the patient in a comprehensible and appropriate language. I consider that I have fully informed the participant of the nature of the study and the possible benefits and risks derived from it, and I believe that the participant has understood this explanation. I have delivered a copy of the information sheet about the study and this document dated and signed to the patient.

Research signature: _____ Date (*): _____
Day / Month / Year

(*)Each signer of the consent must personally write the date of his signature

This document will be signed in duplicate, with one copy left for the researcher and another for the patient.