WRITTEN INFORMED CONSENT FORM

Research project: "Application of Biomarkers of Renal Damage in Patients Treated With Immune Checkpoint Inhibitors"

Study summary

In recent years, the greatest advances against cancer have been achieved with the immunotherapy (treatments that strengthen the immune system's ability to detect and fight the tumour). These drugs include the so-called Immune Checkpoint Inhibitors. Although they have presented significant and long lasting to these new treatments, they are not without side effects. Specifically, kidney damage is especially relevant, since it is associated with a worse evolution of the disease. The problem is that currently the tests Laboratory tests only detect kidney damage when it is already very important and the organ it has lost a large part of its functionality. In this project, it is proposed to look for new tools that alert us to the damage before than the commonly used tests. The urine will be used for analyse biomarkers indicative of that damage and that could appear in an early stage (early biomarkers). Others will also be sought to report the each patient's risk to develop kidney damage before treatment (risk biomarkers). Finally, for cases in which kidney damage appears, they will look for markers that are able to identify the type of damage (markers of differential diagnosis) and thus facilitate the doctor's possible action.

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 were waiting for immunotherapy or combination immunotherapy / platinum compounds

Exclusion criteria

Patients who are terminally ill; Patients who do not wish to sign the informed consent.

Obtainment, collection and processing of urine samples

- Before each antineoplastic cycle
- One week after each antineoplastic cycle

All the samples will be collected in the health centres 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 cannot 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 analyses 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.