

OFFICIAL TITLE: Machine Learning Model to Predict Hospital Length of Stay (HOLS) and Mortality After Discharge in Hospitalized Oncologic Patients [Plantology Database]: a Multicenter Cross-validation Study

NCT NUMBER: NCT ID not yet assigned

13th of August 2020

PATIENT INFORMATION SHEET

Dear patient,

We propose you to participate in the research project entitled: "Multicenter study on clinical and analytical prognostic factors of patients hospitalized in oncology, a holistic approach [Plantology]."

Goals

We request your participation in this project whose purpose is the investigation of clinical, analytical, nutritional factors, psychological status, quality of life and duration of hospital stay as well as survival after hospitalization in order to find improvement measures for the future of our hospitalization and treatment of our cancer patients.

Benefits

There may be no direct benefit to your participation in the study. However, the identification of possible prognostic and/or predictive factors of improvement or worsening of the quality of life and survival of hospitalized patients could benefit other patients in the future and contribute to a better understanding and treatment of patients who require inpatient care.

Study Procedure

We request your authorization for the use of clinical information and blood samples when applicable, which will be kept in the SAP computer system of the Vall d'Hebron Hospital. We will also ask you to answer 2 surveys; one psychological and another on quality of life. The blood samples will be taken coinciding with the requested blood test for healthcare purposes during their hospital stay and in regular outpatient controls. Your sample will only be used in this research project approved by a Research Ethics Committee. At the end of it, it will be destroyed. If you change your mind after submitting your biological samples for study, you may request that your sample be destroyed; To do this, you can contact the PI of the Medical Oncology service.

Discomfort and possible risks

Participating in this study will not cause any additional inconvenience to the secondary of the procedures associated with blood collection and answering 2 surveys; 1 psychological and another about their quality of life.

Place of analysis

The parameters of the blood test will be analyzed in the Medical Oncology Service of the Vall d'Hebron University Hospital and the VHIO (Vall d'Hebron Institut of Oncology).

Personal data protection

If you agree to take part, your doctor will ask you to sign a consent. This means that you agree to participate and that you have no objection that relevant parts of your medical record may be reviewed by authorized personnel for the purposes of the trial. In accordance with current European and national regulations on the Protection of Personal Data, you are informed and consequently consent that your data be included in a file duly

registered with the Spanish Agency for Data Protection in order to carry out the study. of which you have been informed in this document.

Only the data collected for the study will be transmitted to third parties, which in no case will contain information such as name and surname, initials, address, or not from social security. In the event that this transfer occurs, it will be for the same purposes of the study described and guaranteeing confidentiality at least with the level of protection of the legislation in force in our country. If you want to know more about it, you can consult with the principal investigator or contact the Data Protection Delegate. Appropriate measures will be adopted to guarantee the protection of your privacy and your data will not be cross-referenced with other databases that could allow your identification.

In accordance with the rights conferred by current regulations on the Protection of Personal Data, you may exercise your rights of access, rectification, limitation of treatment, deletion, portability and opposition, directing your request to the principal investigator of the study or to the Protection Delegate. of data; directing your request to the email lopdvhio@vhio.net.

In turn, we inform you that you can contact the VHIO Data Protection Delegate by writing to the email address dpd.cliente@conversia.es or by calling 902 877 192.

In accordance with current legislation, you have the right to be informed of the relevant data for your health that is obtained in the course of the study. This information will be communicated to you if you wish; In the event that you prefer not to be informed, your decision will be respected."

If you need more information about this study, you can contact the researcher in charge, Dr. Mirallas of the Medical Oncology Service at omirallas@vhebron.net or by phone at 934 893 000, ext. 6589.

INFORMED CONSENT

Study title: "Multicenter study on clinical and analytical prognostic factors of hospitalized patients in oncology, a holistic approach [Plantology]."

I(name and surnames)
have read the information sheet that has been given to me and I have understood the objectives of the study as well as the potential risks and benefits of my participation in it. I was able to ask questions about the study.

I have spoken with Dr..... I agree to participate according to the established conditions and procedures. I understand that my participation is voluntary. I understand that my participation is voluntary. I understand that I can withdraw from the study: 1. Whenever I want 2. Without having to give an explanation 3. Without this affecting my medical care.

I voluntarily give my consent so that the study can be carried out on possible prognostic factors related to cancer in my blood sample, my clinical-analytical data and on the responses to the surveys carried out. My identity will be kept secret.

I freely give my consent to participate in the study.

Signature Patient, relative or legal representative (indicate)

Investigator Signature

Date

Date