
PATIENT INFORMATION LEAFLET

INFORMED CONSENT FORM

Sponsors: Tatarstan Cancer Center

study code: ESR-17-12934

Center №: << _____ >>

Patient number: << _____ >>

Comparative, multi-centre study estimating association between germline DNA-repair genes mutations and PD-L1 expression level in breast cancer.

We offer you to take part in scientific research. Before you decide whether you want to accept this offer, it is important for you to understand why this study is conducted, how your data will be used and what your participation will consist in. Please, take your time to read the following information and if you want, discuss it with your attending physician.

PREREQUISITES AND STUDY OBJECTIVES

You have been diagnosed with breast cancer; therefore, your doctor has suggested you participate in this study. This is a non-interventional study, participation in which will not require either additional visits to the doctor or any special medical screening, or use of any other medicines besides those which are usually prescribed for your disease.

This study means filling out specially developed medical charts by doctors. During the research the charts will be collected, and the information in them will be carefully analyzed by experts. The purpose of this study is to gather accurate information on presence or absence of association between the presence of hereditary mutations in the genes responsible for DNA damage reparation and the expression rate of protein PD-L1 (which is one of the signs of the tumor immunogenicity) in a tumor, as well as to collect information concerning the prevalence of specific hereditary mutations in DNA reparation genes related to breast cancer in patients of the Republic of Tatarstan and the Republic of Bashkortostan. We expect that the research results will make it possible to improve the quality of medical assistance to patients with such diseases and develop new strategies of treatment in the future.

We are planning to engage 240 patients in 2 clinical centers in the Russian Federation in this research Tatarstan Cancer Center and Republican State Clinical

Oncological Dispensary in Ufa). The project sponsor is Tatarstan Regional Clinical Cancer Center.

Tatarstan Cancer Center will organize and conduct the study, data handling included.

STUDY PROCEDURES

If you decide to participate in this research, your doctor will make necessary entries in your clinical record. Based on your clinical record, the doctor will fill out an individual case report form, i.e. the form which is specially developed for the objectives of this study. For this purpose the doctor will transfer (copy) the following data: your demographic data (gender, date of birth, racial and ethnic origin), data on your disease (including the diagnosis and its details, associated diseases, presence or absence of ovary cancer, breast cancer and other oncology diseases in your family), laboratory and instrumental examination results, including genetic testing results and results of the immunohistochemistry test to determine the expression rate of PD-L1 in tumor tissue. Blood samples will be tested in a special laboratory to determine the presence of a gene mutation specific to this disease. Tumor tissue samples will be examined to determine the expression rate of PD-L1 (no additional healthcare interventions to get such samples will be necessary). The data on mutations obtained as a result of genetic testing will be available to you. The doctor will provide you with these data as soon as the laboratory results become available. The study includes a single (1) visit to the clinic. As a study participant, you are responsible for telling correct information about your past and current medical history to your doctor.

There are a lot of alternatives (as this study is observational and will not require extra procedures or provide any treatment different from routine clinical practice) if you decide not to participate in the study. You should understand that participation in this study will prevent you to participate in any other studies simultaneously.

VOLUNTARY PARTICIPATION IN THE STUDY

You make the decision whether to participate in this research or not. Even if you refuse to participate in the research, it will not lead to any negative consequences for you, including the medical care provided to you. If you decide to participate in this research, you will be offered to sign this Informed Consent Form. Even if you agree to participate, you have the right to withdraw from the research at any time. It will not affect your treatment, either.

You or your legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to your willingness to continue participation in the trial.

The sponsor, ethics committee, regulatory authority or clinic may terminate the study at any time. You will be notified on this decision. As the study is observational it will not have any impact on your medical care.

USE OF PATIENTS' PERSONAL DATA

Handling patients' personal information, its communication and transfer will be carried out according to the Federal law "About Personal Data" No. 152-ФЗ (July 27, 2006).

Signing this Consent Form, you give the Doctor participating in the study and the personnel of the medical center that he / she runs, your consent to collecting and using your personal information for the research ("Research Data"). This information includes your date of birth, your gender, your racial and ethnic origin, personal data on your physical health or condition, including data on genetic traits. Your consent to using your "Research Data" is not limited to a certain term. You can withdraw your consent at any time, informing the Doctor participating in the study.

Research Data which are transferred to the sponsor are protected by a code (hereinafter the Code), not allowing to identify your personal data. The Doctor participating in the research has the key to your Code, by means of which the connection between you and your Research Data is established. The authorized representative appointed by the sponsor, regulatory authorities or other supervisory authorities can check any information in your Research Data, which are kept by the Doctor participating in the research.

The doctor participating in the research will use your Data when carrying out the research. The sponsor may use your Data when carrying out the research and also for the research aimed at developing pharmaceuticals, studying of diagnostics problems or medical care. The institution where the Doctor participating in the research works, and the sponsor institution are responsible for handling your Data according to the legislation of the Russian Federation. The sponsor institution may use your Data together with other institutions of its group, with the institutions providing it with services, as well as with other cooperating companies which may only use your Data for the purposes listed above.

Research results may be published in medical literature, but you will not be identified in the publications.

You have the right to request information from your Research Data that is kept by the Doctor and the sponsor institution. You also have the right to demand that any inaccuracies in this information be corrected. If you have a similar request, please, refer to your Doctor who will help you to contact the sponsor institution if needed.

If you withdraw your consent to participating in this research, your Doctor stops using your Research Data or their transfer to anyone. The sponsor institution may continue using the information which will have been obtained by it before you withdraw your consent.

The confidentiality of your Data will be completely observed as neither your surname, nor your initials will be mentioned in your Case Report Form or any other documents (in particular, the publications based on the information gathered).

The staff of the organization conducting this study will have access to your medical documentation for the purpose of checking the accuracy of filling out the Case Report Forms.

The monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to your original medical records for verification of clinical trial procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations.

Signing this form, you give your consent to using your Research Data as described in this form.

POSSIBLE SIDE EFFECTS, RISKS AND BENEFIT OF PARTICIPATION IN THE STUDY

As no additional examinations and procedures (besides those which are normally carried out in routine practice) are required for this study, there are no specific health risks related to participation in this study.

You will not get any immediate benefit concerning your treatment for your participation in this study. Neither will you get any financial compensation for the participation. Participation in the study will not burden you with any expenses. Nevertheless, information which we expect to obtain as a result of conducting the research can help the academic and medical community to better understand ways to improve medical care for patients with breast cancer.

You can ask the doctor any questions concerning this research, and the doctor will give you clear and detailed answers. If you decide to participate in the study, the doctor will ask you to sign the Informed Consent Form.

ADDITIONAL INFORMATION ON THE RESEARCH

If you need any additional information on the study or the rights of trial subjects, or in the event of trial-related injury, please, refer to:

Doctor (full name):

Phone number:

Address:

or to the Ethics Committee:

Name:

Contact Person:

Phone number:

Address:

INFORMED CONSENT FORM OF THE PATIENT

I have listened to oral information on this study and have read the enclosed written information.

I have been given an opportunity to discuss the research and ask my questions.

I agree to participate in the study and I understand that my decision is completely voluntary.

I understand that I can withdraw from the research at any time, and it will not affect my further treatment.

Signing this Informed Consent Form, I agree that my personal data, including the data concerning my physical health or condition, as well as data on my racial or ethnic origin, including data on genetic traits, may be used as described in this Consent Form, including their transfer to the countries outside Russia.

I agree to provide samples of my tumor tissue and blood for genetic testing to determine the manifestation rate of PD-L1.

I know that I will receive a signed and dated copy of the Patient Information Leaflet and the Informed Consent Form on 6 pages.

Patient Signature

Date

Signed and dated by the patient

Patient Name, Surname (print, CAPITAL LETTERS)

Signature of the person holding
a conversation about the informed consent

Date

Name, surname of the person holding a conversation about the informed consent
(print, CAPITAL LETTERS)