PATIENT INFORMATION LEAFLET

INFORMED CONSENT FORM

A Prospective Randomized Phase II Clinical Trial of Moderately Hypofractionated Radiotherapy (70 Gy in 28 Fractions vs 60 Gy in 20 Fractions) Using Helical Tomotherapy.

Version 1.0

Date 25.01.2019

Sponsors: Tatarstan Cancer Center

study code:

Center №: << _____>>

Patient number: << _____>>

Name, address, telephone number of the medical institution Tatarstan Cancer Center

29, Sibirskiy tract 420029 Kazan, Russian Federation

Chief Researcher: Morov Oleg.

Please carefully read all the information below. If you have any questions, consult a medical doctor.

You are invited to take part in this scientific study, which will be conducted on the basis at.

This patient information leaflet with the informed consent form contains information about what will happen if you participate in this study, information Tatarstan Cancer Center about research objectives and potential risks.

Your participation in this study is voluntary.

If you decide not to participate in this study, it will not affect the level of medical care provided to you within the framework of state programs.

If you decide to participate in this study, you will be asked to sign the informed consent form of this patient information leaflet. You will be given one copy of the patient informed consent form you signed with an informed consent form.

If you decide to participate in this study, you can refuse to participate or leave the study at any time without any sanctions or loss of rights that you have before participating in the study.

To participate in the study, you will need to sign an informed consent form in the presence of the researcher in two copies, one of which will remain with you. You will be given as much time as you need to decide whether or not to participate in the study.

This study will be conducted in accordance with the ethical principles presented in the Helsinki Declaration and in accordance with Russian legislation.

What is the purpose of the study?

Purpose of the study

Compare the results of the two modes of radiation therapy for prostate cancer, at which the dose of radiation delivered in one session, the number of sessions, the total dose of radiation differ.

The duration of irradiation in the first mode will be 4 weeks, during which, for 20 irradiation sessions every day, the total radiation dose of 60 Gy will be summed up.

The duration of irradiation in the second mode will be 5.5 weeks, during which, for 28 irradiation sessions daily, a total irradiation dose of 70 Gy will be summed up.

Our study aims to study the results of radiotherapy for prostate cancer with two different modes of radiation. Both options suggest proven clinical efficacy and safety.

The system of state guarantees provides free civil medical care.

Who can take part in the study?

You can take part in this study if you have a histologically verified adenocarcinoma of the prostate; age over 18 years and available results of the following studies: transrectal ultrasound of the prostate , pelvic magnetic resonance imaging, osteoscintigraphy; clinical stage T1-3N0M0.

There may be reasons that will not allow you to participate in this study. A medical researcher will discuss them with you.

It will be included approximately 300 patients in this study.

What will happen and what is the duration of my participation in this study?

You will be assigned to one of two groups of the prostate cancer radiotherapy regimen. Distribution will occur in a random way - as when tossing a coin. You and your health care provider will know which prostate cancer regimen you are receiving.

You will be asked to undergo radiotherapy for prostate cancer on a TomoHD.

Before radiation exposure, you will undergo a pre-radiation treatment planning computed tomography.

The duration of the course of radiation therapy, depending on the mode of fractionation, will be from 4 to 5.5 weeks.

In the future, you will be monitored by a researcher for 10 years.

This observation may also be in the form of a telephone contact with you. A research doctor or an authorized center employee will contact you during the period of the study to obtain information about your health.

During the study, you will be asked to complete questionnaires assessing your health.

What procedures will be performed if I agree to take part in the study?

During the treatment, in consultation with the attending physician, blood and urine will be collected for analysis.

Pre-radiation treatment planning computed tomography will be carried out by the staff of the Topometric Training Department Tatarstan Cancer Center.

What are the alternative treatment options if I do not wish to participate in the study?

If you decide not to participate in this study or to withdraw your consent to participate in it early, the study doctor may recommend alternative treatments.

An alternative option for radiation therapy is treatment in the traditional radiation regime for 7.5 weeks, for 37 sessions, on linear accelerators SL-75, Synergy.

To participate in the study should:

- read the Patient Information Leaflet carefully, ask all questions you are interested in about the study to the researcher and voluntarily sign the Informed Consent form;

- meet the criteria for inclusion / exclusion in the study;

- provide the research physician with information about your medical and family history;

- provide the results of previous studies,

- there are reasons why you may not be able to participate in this study (for example, in the presence of severe concomitant pathology and other contraindications). Discuss these questions with a medical researcher.

Obligations of the research participant:

- provide the medical researcher with information about your medical and family history;

- provide the results of previous studies;

- agree that a researcher can contact you while you are participating in a study and may have access to your medical documentation for analysis only for the purpose of this study described in this fact sheet;

- fill out questionnaires assessing your health.

How can research procedures affect my well-being, the risks associated with the procedures?

You may experience discomfort while performing certain procedures.

In addition, some of them are associated with certain risks:

Radiation therapy:

- slight weakness, dizziness, nausea, lowering blood pressure.

- a slight decrease in the level of leukocytes and platelets in the blood.

- increased urination, a burning sensation, pains during urination, the appearance of blood in the urine.

- Increased defecation, change in stool consistency, discomfort in the perianal area, lower abdominal pain.

What is my benefit from participating in this study?

Both studied prostate cancer radiotherapy regimens are effective and safe. The results of the study may be important in choosing the mode of irradiation of patients with the radical treatment of localized prostate cancer.

Your actions in case of unforeseen effects of the radiotherapy on your health:

In the case of health complaints, you need to contact a medical researcher.

If there are appropriate indications, you will be entitled to the necessary medical care in the relevant medical institution of the subject of the federation as part of the system of state guarantees of free medical care to citizens. At the same time, the fact of your participation in the study will not provide you with any additional benefits and privileges regarding the list of medical services, the order of their provision, the level of their provision.

Medical care will be provided within the framework of the state guarantee, if you did not participate in the study and handling of health complaints in a public medical institution independently.

If you have a voluntary health insurance policy, medical care may be provided to you in accordance with the terms of such voluntary insurance. Please note that participation in the study may violate the terms of the voluntary medical insurance policy you have and deprive you of the right to receive help with it. In this regard, if you have a valid voluntary medical insurance policy, study its conditions.

What happens if I decide to stop participating in the study?

Your participation in this study is voluntary.

If you decide to stop participating in the study, this will not entail any sanctions or loss of any rights that you had before participating in the study. In the case of your decision to discontinue participation in the study, inform the researcher about this.

In what cases / under what circumstances can participation in the study be terminated?

For various reasons, your participation in the study may be terminated.

These decisions can be made if:

- Continuing to participate in this study does not meet your interests from a medical point of view;

- You do not follow the instructions of your medical researcher;

- The investigation is terminated ahead of time.

Will the privacy of my personal data be protected?

The physician researcher will process your health information that contains personal data, which includes collecting, recording, organizing, storing, storing, specifying, using, transferring, depersonalizing, deleting personal data for conducting this research, in accordance with the conditions set forth in this patient information leaflet.

Such personal data may include your name, address, telephone number, information about past diseases, photographs (pictures of your internal organs) and other research data, including those obtained as a result of medical care within the system of state guarantees of free medical care to citizens. Data may be requested from your doctor or other medical personnel if you have no objections. The physician researcher has the right to process your personal data, including information about your health. In accordance with the legislation of the Russian Federation, the doctor is obliged to maintain the confidentiality of these data.

The protection of your personal data is guaranteed during the entire study and after its completion. After signing an informed consent, participants will be assigned unique identification numbers. The personal data of the participants, as well as the associated identification numbers, will be stored with the medical researcher and will not be accessible to third parties. All research data obtained during

participation in the study are part of a scientific study and can be used to present the results in scientific publications and public reports (conferences, symposia, defended candidate and doctoral theses), without violating the confidentiality of your data, that is, that does not allow to identify your identity (without specifying the last name, first name, patronymic and other data that allow you to be associated with the presented results).

Your permission to use and transfer your health data is indefinite.

You can at any time withdraw your consent to the use and transmission of data about your health by sending a written notice to the investigator about this. However, after this you will be excluded from the study.

If you have questions about specific medical information about your health that will be used during this study, you can discuss them with a medical researcher.

Who / where can I ask questions?

For questions:

Concerning the study

Medical researcher

Full name

Tel: +7 (843) _____

Cell: + _____

Concerning my rights as a research participant:

Local ethical committee Tatarstan Cancer Center

29, Sibirskiy tract 420029 Kazan, Russian Federation

Tel: +7 (843) 202-23-86

This scientific study was approved by the Expert Council and the Local Ethics Committee Tatarstan Cancer Center.

Informed Consent Form

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Version 1.0

Date 25.01.2019

Sponsors: Tatarstan Cancer Center

study code:

I, _____

Patient Name, Surname (print, CAPITAL LETTERS)

Contact Information_____

Tel.

Informed with a medical researcher

_____

Name, Surname

about all aspects of the planned research and give my free and informed consent to participate in this study.

By signing this form, I confirm the following:

I have read and understood this patient information sheet.
I received full information about the methodology, objectives, planned procedures and risks of the study from the physician researcher.

I had (a) the opportunity to ask and discuss with the researcher all the questions I am interested in and received (a) comprehensive answers to them.

I agree to follow the instructions, cooperate voluntarily with a medical researcher.

I confirm my consent to participate in this study.

I understand that participation in this study is voluntary.

I can refuse to participate in the study both now and at any time, for which I must (on) report this to the physician to the researcher, and this will not entail any sanctions or loss of any rights that I had before participating in the study.

I can be excluded (on) from the study without my consent to this in case of non-compliance with my research plan, or for other reasons.

I give permission to use and transfer my health data in accordance with the information provided in this patient information leaflet.

Patient Name, Surname (print, CAPITAL LETTERS)

Patient Signature

Date

Medical Researcher Name, Surname (print, CAPITAL LETTERS)

Medical Researcher

Date