MEDICALPOINT

INFORMED CONSENT FORM FOR ^{18}F-FDG PET/CT (POSITRON EMISSION TOMOGRAPHY / COMPUTED TOMOGRAPHY) (PET CT BİLGİLENDİRME)

Patient No : .....
Name Surname : .....
Gender : ☐ K ☐ E
Date of Birth : ...../...../.....
Department : .....
Date : ...../...../.....

Dear Patient /Legal Representative;
You have the right to be informed about your health status (health status of your patient) and also about any and all procedures for medical or surgical treatment or the diagnosis of your disease (the disease of your patient), their alternatives, the benefits, risks and even the possible damages and to refuse or accept them completely or partially and to discontinue them at any stage.
We ask you to read and understand this form which is issued for informing you and obtaining your consent in order to determine whether you give your consent or not, and thus, it does not intend to frighten you or make you avoid medical procedures.

INFORMATION
PROVISIONAL DIAGNOSIS : .....
PLANNED TREATMENT/ESTIMATED DURATION : .....

Your physician recommended this test to identify all aspects of your disease and to manage your treatment. At our Clinic, PET/CT will be scanned with 18-FDG (fluorodeoxyglucose) for you. This form is prepared to inform you in detail about considerations before and after the examination. This radioactive substance is administered to make diagnosis. A large part of radioactive substances is excreted by feces, urine and body fluids, such as saliva and sweat. After the examination is completed, you should take some additional measures for 8 hours to protect those around you.

WARNINGS

Please let us know before any action is taken, if you are pregnant or if you have doubts about being pregnant. This technique cannot be performed for pregnant patients and patient's with suspected pregnancy. Your party is responsible if these situations are not notified.
Please inform our party if you have a baby and if you are breast feeding.
Pregnant individuals and small children should be avoided for 1 day after the procedure. Please follow all instructions of healthcare personnel to ensure that examination is optimal and correct.
18F-FDG used for the examination is completely concordant with the human's biological structure and it has no known allergic or side effect. Please inform our party in case of a problem.
The radioactive substance to be administered for the examination is special production and it is sent to our clinic on a daily basis. In some circumstances, problem regarding production or transfer of the substance may occur. The examination may be postponed in such rare circumstances that may be experienced on the day of the examination.

PREPARATION

Please bring other examination results (pathology report, CT, MRI, ultrasound, PET, etc.) relevant to your disease when you present for examination.
You need to stop eating and drinking 4 to 6 hours before the procedure. You can drink water. Bring 1 liter of water with you. Wear comfortable garments without metal accessories.
You do not need to discontinue routine medications before the procedure. However, anti-diabetic agents may compromise the PET images. Therefore, please inform us in advance if you are diabetic.

PROCEDURE

Your blood glucose will be measured before the drug is administered. The examination may be postponed if it is tested high.
FDG which is equivalent to glucose molecule in human body will be injected into a blood vessel.

Name & Surname of Patient or Legal Representative
Full Name ..... Signature .....

After the agent is administered, you need to rest in a room approximately for 45-60 minutes in order to ensure optimal distribution of the agent in the body. No one, including your family members, is allowed to this room at this time interval, unless it is strictly necessary.
F-18 FDG, accumulates in all tissues, where the metabolism increases. Therefore, it is very important to avoid moving and speaking to the maximum extent within the resting period.
Next, your imaging study will be started and it will take around 15 to 25 minutes.
You should not move throughout the imaging study. When you move or it is necessary to pause the imaging, it will be required to re-start the scanning.
Extra imaging may be required and total duration of scanning may prolong, if the nuclear medicine physicians deems necessary.
All obtained data are processed in computers after the examination is finished.

AFTER EXAMINATION

Drink plenty of water (about 3 lt) for 6-8 hours if you do not have kidney failure. (Drink as much water as advised if you have kidney failure)
Take a shower after you arrive at your home if possible.
Pour plenty of water to the toilet after using it within the first 8 hours.
Avoid close contact with pregnant individuals, babies and children for 8 hours.
Stop breastfeeding your baby for 8 hours, harvest your breast milk intermittently and dispose of the contents.
Dispose of the first harvest after 8 hours and wait for the next milking period to breastfeed your baby.
Avoid crowded placed for 8 hours (school, kindergarten, cinema, theatre, a house of worship etc.)
Do not visit your doctor immediately after the procedure, if your doctor has no special request or there is no emergency.
The effect of the radioactive substance will near totally disappear next day. You can continue your daily life.

How to access medical aid for same condition, when necessary:

Refusal of treatment/surgery is a decision that you should make on your own. If you change your mind, you can present again to our hospital or other hospitals that can perform relevant treatment/surgery.

Specific Conditions:

Allergy/Current Medications: I informed my physician about all my known allergies. Moreover, I informed my physician about current prescribed and over-the-counter drugs, herbal medicines, diet additives, illicit drugs and alcohol and illegal drugs/sedatives. I am informed by my physician about pre- and post-operative effects of those agents, and recommendations are made.

Tobacco and Tobacco Products: I am informed that pre- and post-operative smoking status (cigarette, shisha, cigar, tobacco pipe etc.) may prolong duration of improvement. I am aware that if I use any of above substances, the risk of wound healing problems will be higher.

Use of Tissue: Any tissue not required for medical diagnosis, but also required for treating my condition may be used for medical research should the tissue is used under ethical consideration, use of tissue is reviewed by the ethics committee and the research is approved. I consent that research results can be published in medical literature should my personal details are kept confidential. I am aware that I may refuse participation to such study and this refusal may no means negatively influence my treatment. I consent to use of any tissue, medical device or body parts which may be extracted during surgical procedure.

Medical research: I consent that clinical information from my medical records are reviewed to contribute to medical studies, medical researches and training of physicians, my data and information are shared with students pursuant to Personal Data Protection Law (KVKK), examinations and procedures are watched, applied and followed by students. I consent that research results can be published in medical literature should my personal details protected pursuant to Personal Data Protection Law. I am aware that I may refuse participation to such study and this refusal may by no means negatively influence my treatment.

Name & Surname of Patient or Legal Representative
Full Name ..... Signature .....

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Photograph/Observers: For all diagnostic, workup, treatment and rehabilitation processes at your hospital, I know that this institution is a university hospital and I give my explicit consent that the operation and suitable parts of my body are photographed for scientific, medical or educational purposes, shared with students or photographs are taken, video and voice recordings are made only for educational purposes and those records and my medical information are used in studies and in courses pursuant to Personal Data Protection Law.

Phone: Please call 0232-3995050

When you present to Emergency Medicine Department for emergencies out of office hours, we are notified about your request.

Patient details the physician should know:
Current Medications:
Bleeding time:
Allergy:
Other diseases:

Notes of physician about information session:
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Consent statement of the patient, parent or curator:

- My physician made necessary explanations about my health condition.
- I am informed in detail about what the planned treatment/intervention is, its necessity, course of the procedure and other treatment options as well as their risks, possible outcomes if I refuse the treatment, success rate of the treatment and the side effects.
- I read and understood the issues requiring my attention before and after the treatment/intervention.
- I am informed that all documents filed about me in the course of diagnosis/treatment/intervention and specimens sampled can be used for training purposes.
- My physician provided satisfactory answers to all my questions.
- I am informed about the team involved in the treatment/intervention.
- I am conscious and I feel that I am qualified to make my own decision.
- I understood that I am not obliged to consent to the treatment/intervention if I do not want and/or I may stop the procedure at any stage.

Name & Surname of Patient or Legal Representative
Full Name ..... Signature .....

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APPROVAL

I read the above written information and I am informed by the undersigned physician. I am informed about aim, risks, complications and alternatives of the proposed procedure. I give consent to the procedure on my free will without requiring extra explanation.

I, hereby, authorize ..... (please insert legal representative) to be informed about my treatment and give consent to all necessary procedures if I am unconscious or am mentally incapable to consent. (The legal representative of the patient should undersign).

(Please hand write "I understood what I read and I agree all explanations) .....

Patient Signature Date / Time

Name & Surname (hand writing) .....

If the patient is not capable to give consent:

Legal representative of the patient Signature Date / Time

Name & Surname (hand writing) .....

Reason for inability to take consent from the patient (to be filled in by physician):

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.....

I, the undersigned, provided the patient/legal representative written above with sufficient and satisfactory information on the disease, the proposed procedure, underlying cause and benefits of the procedure as well as postoperative care, possible risks, type of anesthesia, if it will be induced, and complications. By voluntarily signing this form, patient/legal representative confirms that s/he is adequately informed about the procedure.

Doctor Signature Date / Time

Name-Surname: .....

If the patient has language/ communication problem;

I had interpreted the instructions of the physician in a manner understandable by the patient. In my opinion, the interpreted information is understood by the patient.

Interpreted by Signature

Date / Time

Name Surname (handwrite): .....

You may apply to Patient Relations Department during office hours or to Management On Duty at night for all your complaints and any other considerations you need to be addressed.

*Legal Representative: The legal representative implies the curator for subjects who are under guardianship, the mother and father f or minors and the first degree legal heirs if said subjects are not available. Signing this consent form shall not imply that legal rights of the patient are waived.

Name & Surname of Patient or Legal Representative

Full Name ..... Signature .....

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Name - Surname
Date of Birth
Patient No
Protocol No

INFORMED CONSENT FORM FOR CYSTECTOMY + URINARY DIVERSION (SİSTEKTOMİ + ÜRİNER DİVERSİYON)

Dear Patient /Legal Representative;
You have the right to be informed about your health status (health status of your patient) and also about any and all procedures for medical or surgical treatment or the diagnosis of your disease (the disease of your patient), their alternatives, the benefits, risks and even the possible damages and to refuse or accept them completely or partially and to discontinue them at any stage.
We ask you to read and understand this form which is issued for informing you and obtaining your consent in order to determine whether you give your consent or not, and thus, it does not intend to frighten you or make you avoid medical procedures.

INFORMATION

PROVISIONAL DIAGNOSIS : .....
PLANNED TREATMENT / ESTIMATED DURATION : .....

If the surgery is performed due to urinary bladder tumor, urinary bladder, prostate, seminal vesicles, lymph nodes of male patients and uterus, ovaries and anterior 2/3 part of vaginal wall of female patients are removed with 30-35 cm incision on abdomen and pelvis under general anesthesia. Lymph nodes are routinely removed and sent for pathologic examination together with the urinary bladder in order to define the stage of the cancer. If the surgery is performed for neurogenic bladder, enterovesical or vesicovaginal fistula or trauma, only the urinary bladder is removed. After urinary bladder is removed, a 15-20 cm part of small intestine is removed and used to form a new urinary bladder. The new urinary bladder formed from the intestine is anastomosed to right side of umbilical region depending on the condition (stage of disease, patient's age, general status of health, need for extra treatment etc.) or it is placed to the location of old bladder and re-anastomosed to urethra. If the urinary diversion is performed by placing the new urinary bladder at location of the old one, the patient can urinate via normal route (orthotopic urinary diversion). If the new urinary bladder is anastomosed to the skin, a bag and valve system is placed to the anastomosis site and it is ensured that the urine spontaneously discharges to the bag or in presence of continent diversion, the patient can discharge the urine by placing the catheter through the hole in skin 4 to 6 times a day. At the end of surgery, two drains are placed in new bladder and two drains are placed at the location in abdomen from which bladder is removed. If orthotopic bladder is constructed, one urethral catheter is additionally placed. Vasectomy procedure is routinely performed.

B - ANESTHESIA

Please see information sheets titled "About Anesthesia" in order to get information about the anesthesia and relevant risks. If you have any concern, you may discuss the issue with your anesthesiologist. If infor- mation sheet is not provided to you, please request one.

C- OVERALL RISKS OF OPERATION

a-Small airways may be occluded, resulting in the increased risk of pulmonary infection. Antibiotherapy and

Name & Surname of Patient or Legal Representative
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15- Patients may not ejaculate semen as seminal vesicle and the prostate are removed and vasectomy is performed.

16- Risks of the wound infection, lung infection, cardiopulmonary complications and the thrombosis are higher in obese patients. What you should know about the disease: In presence of urinary bladder tumor, there is tumor in your urinary bladder and surgery is performed for completely eliminating this cancer or for preventing the cancer from spreading to entire body or for salvage purpose due to swelling in kidneys, uncontrollable bleeding, compression on large vessels or compression on nearby organs caused by the disease.

Removal of urinary bladder and urinary diversion are necessary to protect the kidneys, to prevent urinary incontinence and to control infection in presence of neurogenic bladder, enterovesical or vesicovaginal fistula and the operation is necessary in case of trauma when it is not possible to repair the bladder and control the bleeding.

What may happen if the procedure is refused?:

In case of urinary bladder tumor, hematuria may worsen. The patients may need blood transfusion or emergency cystectomy or percutaneous angioembolization may be needed. The blood clots may occlude the urinary tract and an additional surgery may be needed. Cancer may spread outside of urinary bladder.

It may first spread to surrounding tissues, then to entire body with blood and lymphatic route and cause death. In case of neurogenic bladder, enterovesical or vesicovaginal fistula, infection may develop; it may not be possible to control the infection and the infection may affect the kidneys and blood. It may result in renal dysfunction in long term. It may not be possible to prevent urinary incontinence and complications secondary to it may be seen. In case of trauma, bleeding may not be controlled and it may result in death.

What kind of a treatment will be applied (it should include information about alternative treatments):

If the surgery is performed due to urinary bladder tumor, urinary bladder, prostate, seminal vesicles, lymph nodes of male patients and uterus, ovaries and anterior 2/3 part of vaginal wall of female patients are removed with 30-35 cm incision on abdomen and pelvis under general anesthesia. Lymph nodes are routinely removed and sent for pathologic examination together with the urinary bladder in order to define the stage of the cancer. If the surgery is performed for neurogenic bladder, enterovesical or vesicovaginal fistula or trauma, only the urinary bladder is removed. After urinary bladder is removed, a 15-20 cm part of small intestine is removed and used to form a new urinary bladder. The new urinary bladder formed from the intestine is anastomosed to right side of umbilical region depending on the condition (stage of disease, patient's age, general status of health, need for extra treatme nt etc.) or it is placed to the location of old bladder and re-anastomosed to urethra. If the urinary diversion is performed by placing the new urinary bladder at location of the old one, the patient can urinate via normal route (orthotopic urinary diversion). If the new urinary bladder is anastomosed to the skin, a bag and valve system is placed to the anastomosis site and it is ensured that the urine spontaneously discharges to the bag or in presence of continent diversion, the patient can discharge the urine by placing the catheter through the hole in skin 4 to 6 times a day. At the end of surgery, two drains are placed in new bladder and two drains are placed at the location in abdomen from which bladder is removed. If orthotopic bladder is constructed, one urethral catheter is additionally placed. Vasectomy procedure is routinely performed. In case of urinary bladder tumor, it may be tried to control the disease with chemotherapy and/or radiotherapy to protect the urinary bladder for selected patients. Percutaneous angioembolization may be needed for bleeding. In other cases, cystectomy is performed as the last option for treatment.

Postoperative radiotherapy or chemotherapy can be performed for selected patients in case of urinary bladder tumor.

Questions of the patient about type of the procedure, timing, side effects and the success rate as well as

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