

POSITRON EMISSION TOMOGRAPHY (PET) POSITRONEN-EMISSIONS-TOMOGRAPHIE (PET)

Information and medical history for adults and young patients for preparation of an informative interview with the doctor

Klinik / Praxis



Data about the patient: Patientendaten:

englisch

- with contrast medium mit Kontrastmittel
 orally oral intravenously intravenös

administered substance verabreichte Substanz: _____

on (date): am (Datum): _____

region of the body to be examined zu untersuchende Körperregion: _____

Dear patient,

In order to determine the cause of your symptoms, for the purpose of aftercare or for further treatment planning, a nuclear medicine procedure is planned in your case, a so-called **positron emission tomography** (PET scan).

This form will serve to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you the advantages and disadvantages of the scheduled procedure compared with alternative methods available, and inform you of any risks specific to your case. The doctor will answer all of your questions in order to reduce any fears or concerns you may have. You may then consent to the procedure suggested to you. Your doctor will provide you with a copy of the completed and signed form after the interview.

Not all insurers cover a PET scan. It is therefore advisable to check with your health insurance company prior to the procedure to find out whether they will cover the costs.

HOW A PET-CT SCAN WORKS

FUNKTIONSWEISE DER PET-CT

Positron emission tomography is a diagnostic procedure which can depict metabolic processes within the body with precision.

To prepare you for the scan, a radiolabelled substance will be administered to you, for instance in a sugar solution. The substance will accumulate in regions of the body with a high level of metabolic activity (such as tumours). The PET scanner will register the radiation emitted by the body and create three-dimensional images of the region to be examined. This allows for a nidus, e.g. in the bones, lungs or the intestine, to be localised and diagnosed with precision.

For improved imaging results, a PET scan is combined with a computer tomography (CT) scan (PET-CT). For CT imaging, drinking an iodine-containing contrast medium may be required. If the contrast medium is injected, you may feel a warm sensation spreading throughout your body and disappearing after a few seconds.

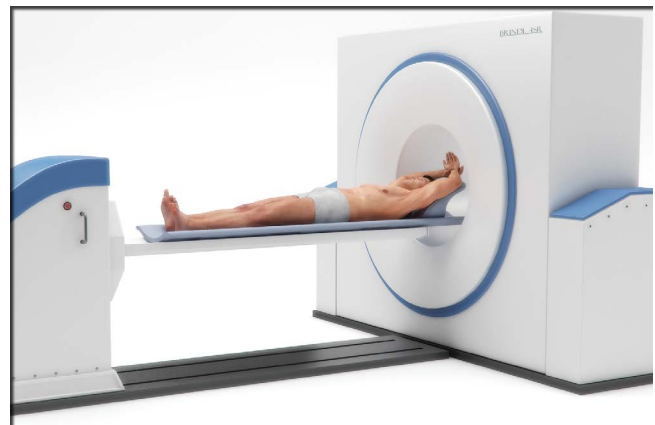
COURSE OF EXAMINATION UNTERSUCHUNGSABLAUF

Approximately one hour before the examination, the radioactive substance will be administered via a peripheral venous cannula. This period of time is necessary in order for the substance to be able to reach the target tissue. You should avoid moving around too much during this waiting period since the substance could then accumulate mostly in your muscle tissue, thus distorting the imaging results.

For the imaging procedure, you will lie down on an examination table and be slowly navigated into the PET scanner. You will have to lie still during the entire examination, which can take between 20 - 60 minutes depending on the area to be examined, in order for precise images to be taken. If you have problems lying still for an extended period of time due to an illness, please inform

your doctor beforehand in order for preparations to be made accordingly for the scan.

For certain examinations, a urinary catheter will have to be inserted in order to facilitate imaging of the lesser pelvis. Your doctor will let you know whether this procedure is planned in your case.



ALTERNATIVE METHODS ALTERNATIV-VERFAHREN

Useful images of anatomical structures and organs can be generated by using ultrasound, X-ray, MRI or CT scanning. However, those imaging methods provide no or little clues when it comes to metabolic processes or the function of organs and therefore do not constitute a viable alternative to a PET scan. In the area of tumour diagnosis, a PET scan is also often more precise than other imaging methods. Your doctor will explain the alternative methods to you and also why he deems a PET scan to be the most effective method in your particular case.

ADVICE FOR PREPARATION AND AFTERCARE

HINWEISE ZUR VORBEREITUNG UND NACHSORGE

Unless specifically instructed otherwise, please adhere to the following guidelines: Instructions for preparation and aftercare may vary, depending on the type of procedure.

Preparation:

Please bring any previous X-ray or CT images or findings with you.

Medication: Please inform your doctor of any medication you take or inject on a regular basis. Please also cite any medication (over-the-counter or herbal remedies) you have recently taken from time to time. Your doctor will let you know if and for how long you should stop taking your medication.

A PET scan requires **pre-procedure fasting**. Therefore, you may not eat or drink anything for at least six hours prior to the procedure and must refrain from smoking. Clear fluids in small amounts (e.g. non-carbonated water or unsweetened tea with no milk or cream) are allowed until shortly before the procedure.

Some examination procedures may require the administration of **antispasmodics**. Your doctor will inform you accordingly if this applies to you.

Any **metal objects**, e.g. mobile phones, glasses, watches, jewellery, hairpins, hearing aids, coins, keys, piercings, removable dental prosthetics etc., must be removed before the examination.

After the radioactive substance has been administered to you and prior to the scan, you should **move around as little as possible** and **drink plenty of fluids**. Your doctor will provide you with specific instructions.

If you are **pregnant**, a PET scan cannot be undertaken. Please let your doctor know if there is a possibility that you might be pregnant.

Please also let your doctor know if you are currently **nursing** since the radioactive substances administered for a PET scan can pass into breast milk, meaning you should not nurse your baby for a certain period of time after the procedure.

Some pre-existing conditions require certain **lab values**, such as **kidney** or **thyroid values**, to be examined prior to a **CT scan** with **administration of a contrast medium**. Your doctor will let you know well in advance if this applies to you.

Aftercare:

After the PET scan, it may also be necessary to **drink plenty of fluids** in order to flush out the radioactive substance via the kidneys. Your doctor will provide you with specific instructions.

On the day of the examination, you should **avoid close contact with pregnant women or children**.

If a sedative and/or analgesic has been administered to you, you must be collected by an adult if the examination has been performed **on an out-patient basis**. Also, for a period of **24 hours after the procedure**, you must not actively participate in road traffic (not even as a pedestrian), refrain from any risky activities and avoid taking any important decisions, unless otherwise instructed.

If **further nuclear medicine examinations/procedures** are to be performed at a later point in time, please inform your doctor that you have undergone a PET scan.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

RISIKEN, MÖGLICHE KOMPLIKATIONEN UND NEBENWIRKUNGEN

It is well known that **any medical procedure is accompanied by certain risks**. However, a PET scan is a low-risk routine procedure. Please understand that, for legal reasons, any possible risks associated with this procedure must be listed, even if some of these only occur in exceptional cases. During the interview, your doctor will inform you of any risks specific to your case. You

may also choose to waive a detailed explanation. In that event, please pass over this section on risks and confirm your waiver with your signature in the final section of this form.

Radiation exposure through a PET scan is low. It amounts to approx. two or three times the level of the average annual exposure to radiation, so that radiation damage is unlikely even if the procedure is repeated. The risk of getting cancer (such as leukaemia) after years or decades may be slightly increased. If a CT scan is performed in addition to the PET scan, radiation exposure is still low owing to the modern scanners used nowadays, but still higher than during a normal X-ray. However, a CT scan will only be undertaken if its benefits justify the radiation exposure it is accompanied by. It is important for you to inform your doctor of any previous X-ray examinations in order to keep the overall radiation exposure within a certain time period at the lowest possible level.

Allergic reactions, for instance to the radioactive substance administered, to contrast media or medication, can lead to skin rash, itching, swelling, nausea and coughing. Severe reactions such as shortness of breath, spasms, tachycardia or **life-threatening circulatory shock** are rare. They may then result in permanent organ damage, such as brain damage, paralysis or kidney failure requiring dialysis.

Bruising (haematomata) sometimes occurs at or around the puncture sites. This may lead to firm, painful swelling. Most of the time, this will disappear after a few days or weeks even without treatment.

Damage to the skin, soft tissue or nerves (for instance through injections or despite proper positioning) is rare. Paresthesia, sensory disturbance, numbness, paralysis and pain may then result. These symptoms usually disappear without treatment or can be treated successfully. On rare occasions, these symptoms may persist, or scars may remain.

Infections at an injection site, including syringe abscess, tissue death (necrosis) or vein inflammation (phlebitis), rarely occur. In most cases, such infections can be treated successfully with antibiotics. In extreme and exceptional cases, an infection that has spread beyond control can lead to **life-threatening blood poisoning** (toxaemia).

If a urinary catheter has been inserted, it may lead to **bladder infections** or, in very rare cases, to injury of the bladder wall.

The administration of **antispasmodics** can lead to a drop in blood pressure, an increase of the heart rate, urinary retention, glaucoma attack in patients with glaucoma and to symptoms such as nausea, tiredness and dizziness.

Specific risks related to the administration of contrast media

If a contrast medium is administered, patients already suffering from kidney disease may experience a **decrease in kidney function**. However, this can usually be treated by increasing one's intake of fluids or administering medication. If the kidneys were already severely damaged, a patient may suffer **kidney failure**, leading to permanent dialysis becoming necessary.

Diabetics who are on biguanides such as Metformin may experience **dangerous disturbances of the metabolism** (acidosis). Patients with dysfunction of the thyroid gland may experience **hyperfunction of the thyroid**, so-called hyperthyreosis, due to the use of iodine-containing contrast media. This will lead to tachycardia, hot flushes, restlessness and diarrhoea.

Questions about Your Medical History Please fill in the following questionnaire carefully before your information talk. **Please tick the applicable box!** It goes without saying that your information will be treated confidentially. The information you provide will help the physician to better assess the risks of treatment in your particular case, to advise you on the complications that could occur, and to take any steps needed to prevent complications and side effects. **yes=ja no=nein**

Gender: M / F, **age:** _____ **years, weight:** _____ **kg, height:** _____ **cm**
 Geschlecht: m / w, Alter: Jahre, Gewicht: kg, Größe: cm,

Have you ever had a PET? yes no
 Wurde bei Ihnen schon einmal eine PET durchgeführt?

If so, which ones? _____
 Wenn ja, welche?

Have you ever had a CT scan, for instance during an earlier hospitalisation? yes no

Haben Sie schon einmal eine Computertomographie, z. B. bei einem früheren Krankenhausaufenthalt, erhalten?

Which area(s) or your body was (were) checked-up?

If you have an X-ray card, please bring it with you.

Welche Region(en) Ihres Körpers wurden hierbei untersucht? **Sollte ein Röntgenpass vorliegen, bitte mitbringen!**

Have you ever had testing/ therapy with radioactive substances? yes no

Wurde bei Ihnen schon einmal eine **Untersuchung/Behandlung mit radioaktiven Stoffen** durchgeführt?

If so, when and what testing/therapy?

Wenn ja, wann und welche?

Information about medications:

Do you regularly require blood thinning medications (anticoagulants) or have you taken any or have any been injected during the past 8 days? yes no

Aspirin (ASS), Clopidogrel, Heparin, Marcumar®, Plavix®, Ticlopidin.

Angaben zur Medikamenteneinnahme: Benötigen Sie regelmäßig blutgerinnungshemmende Mittel oder haben Sie in der letzten Zeit (bis vor 8 Tagen) welche eingenommen bzw. gespritzt? Aspirin® (ASS), Clopidogrel, Heparin, Marcumar®, Plavix®, Ticlopidin.

Any other: _____
 Sonstiges:

When did you take the last dose? _____
 Wann war die letzte Einnahme?

Do you take any other medications? yes no

Werden andere Medikamente eingenommen?

If so, which ones: _____
 Wenn ja, bitte auflisten:

(Please include non-prescription medications, herbal and other natural remedies, vitamins, etc.) (Auch rezeptfreie Medikamente, natürliche oder pflanzliche Heilmittel, Vitamine, etc.)

Are you pregnant? not certain yes no
 Sind Sie schwanger? nicht sicher

Are you currently breast feeding a baby? yes no
 Stillen Sie?

Do you have pain or other complaints causing problems during lying flat or standing upright? yes no

Haben Sie Schmerzen oder andere Beschwerden, sodass Sie Probleme beim Liegen oder Stehen haben?

Do you have or have you ever had any of the following diseases or symptoms thereof?

Liegen oder lagen nachstehende Erkrankungen oder Anzeichen dieser Erkrankungen vor: Blutgerinnsel (Thrombose)/Gefäßverschluss (Embolie)?

Allergies / Oversensitivity? yes no

Medications, foods, contrast media, iodine, sticking plaster, latex (e.g. rubber gloves, balloons), pollen (grass, trees), anaesthetics, metals (itching caused by metal spectacles frames, jewellery, jeans buttons).

Allergie/Überempfindlichkeit? Medikamente, Lebensmittel, Kontrastmittel, Jod, Pflaster, Latex (z.B. Gummihandschuhe, Luftballon), Pollen (Gräser, Bäume), Betäubungsmittel, Metalle (z. B. Juckreiz durch Metallbrillengestell, Modeschmuck oder Hosennieten).

Any other: _____
 Sonstiges:

Do you have a malignant tumour (cancer)? yes no

Leiden Sie an einer Tumorerkrankung (Krebs)?

Have you ever had radiation therapy or chemotherapy? yes no

Erhielten Sie eine Strahlen- oder Chemotherapie?

Metabolic diseases? yes no

Diabetes (sugar sickness), Gout.

Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Gicht.

Any other: _____
 Sonstiges:

Thyroid diseases? yes no

Underactive thyroid, overactive thyroid, Nodes, Hot thyroid nodule, Inflammation, Thyroid gland operations, Thyroid gland cancer. **Schilddrüsenerkrankungen?** Unterfunktion, Überfunktion, Knoten, Kropf, Entzündung, Schilddrüsenoperation, Schilddrüsenkrebs.

Any other: _____
 Sonstiges:

Kidney diseases? yes no

kidney insufficiency, kidney inflammation, Kidney operations, Plasmocytoma, Kidney or ureter stones, Blood in the urine, Dialysis. **Nierenerkrankungen?** Nierenfunktionsstörung (Niereninsuffizienz), Nierentzündung, Nieren-OP, Plasmozytom, Nieren-oder Harnleitersteine, Blut im Urin, Dialyse.

Any other: _____
 Sonstiges:

Communicable (contagious) diseases? yes no

Hepatitis, tuberculosis, HIV.

Infektionskrankheiten? Hepatitis, Tuberkulose, HIV.

Any other: _____
 Sonstiges:

Any other acute or chronic diseases / illnesses? yes no

Nicht aufgeführte akute oder chronische Erkrankungen?

Please describe: _____
 Bitte kurz beschreiben:

If certain answers are preselected, please correct them if anything has changed.)

Important Questions for Outpatients

Wichtige Fragen für ambulante Eingriffe

Who will pick you up when you are discharged from the hospital/ clinic/surgeon's practise? Wer wird Sie abholen, sobald Sie aus Klinik/Praxis entlassen werden?

Name and age of the person picking you up: [Name und Alter des Abholers]

Where can you be reached within the 24 hours after surgery?
Wo sind Sie in den nächsten 24 Stunden nach dem Eingriff erreichbar?

Street, house number, postcode, place: [Straße, Hausnummer, PLZ, Ort]

Telephone: [Telefonnummer]

Name and age of person looking after you: [Name und Alter der Aufsichtsperson]

Who is your physician (the one whose care you are in/who referred you/family surgeon)? Wer ist Ihr überweisender Arzt / Hausarzt / weiter betreuender Arzt?

Name: [Name]

Street, house number: [Straße, Hausnummer]

postcode, place: [PLZ, Ort]

Telephone: [Telefonnummer]

Information regarding radiation protection in accordance with section 85 of the German Radiation Protection (StrlSchV) Informationen zur Strahlenschutzverordnung nach §85 StrlSchV

Patient's name Patientenname: _____

Date of examination Datum der Untersuchung: _____

Result of questioning regarding previous examinations/treatment involving radioactive substances or ionising radiation:
Ergebnis der Befragung zu früheren Untersuchungen/Behandlungen mit radioaktiven Stoffen oder ionisierenden Strahlen:

Result of questioning regarding pregnancy or nursing for women of childbearing age: Ergebnis der Befragung über Schwangerschaft oder Stillen bei gebärfähigen Frauen: _____

Type and purpose of examination: Art und Zweck der Untersuchung: _____

Type and composition of the injected substance: Art und Zusammensetzung der injizierten Substanz: _____

Activity of the administered substance (in MBq): : Aktivität der verabreichten Substanz (in MBq): _____

Radiation exposure (in mSv): Strahlenexposition (in mSv): _____

Medical documentation for the informative interview

Ärztl. Dokumentation zum Aufklärungsgespräch

To be completed by the doctor Wird vom Arzt ausgefüllt

Über folgende Themen (z. B. mögliche Komplikationen, die sich aus den spezifischen Risiken beim Patienten ergeben können, nähere Informationen zu den Alternativ-Methoden, mögliche Konsequenzen, wenn die Untersuchung verschoben oder abgelehnt wird) habe ich den Patienten im Gespräch näher aufgeklärt:

with contrast medium mit Kontrastmittel

orally oral intravenously intravenös

administered substance verabreichte Substanz: _____

Capability to give wilful consent:

Fähigkeit der eigenständigen Einwilligung:

The patient is capable of making a decision on the recommended procedure by himself/herself and issuing its consent for the procedure. Der/Die Patient/in besitzt die Fähigkeit, eine eigenständige Entscheidung über den empfohlenen Eingriff zu treffen und seine/ihre Einwilligung in den Eingriff zu erteilen.

The patient is represented by the carer, i.e. guardian with a document of evidence of guardianship. This person is entitled to making a decision on behalf of the patient.

Der/Die Patient/in wird von einem Betreuer bzw. Vormund mit einer Betreuungsurkunde vertreten. Dieser ist in der Lage, eine Entscheidung im Sinne der Patienten zu treffen.

City, date, time [Ort, Datum, Uhrzeit]

Doctor's signature [Unterschrift der Ärztin/des Arztes]

Refusal by the patient Ablehnung des/der Patienten/in Ms./Mr. _____ has provided me with detailed information regarding the suggested PET scan and has also pointed out the disadvantages of rejecting it. I have understood the information provided to me and reject the PET scan suggested to me.

Frau/Herr Dr. ___ hat mich umfassend über die vorgeschlagene PET und über die sich aus meiner Ablehnung ergebenden Nachteile aufgeklärt. Ich habe die diesbezügliche Aufklärung verstanden und lehne die mir vorgeschlagene PET ab.

City, date, time [Ort, Datum, Uhrzeit]

Signature of the patient/guardian/tutor/possible witness
[Unterschrift der Patientin / des Patienten / Betreuer / Vormund / ggf. des Zeugen]

Patient statement and declaration of consent

Erklärung und Einwilligung des/der Patienten/in

Please tick the appropriate boxes and confirm your statement with your signature below:

I hereby confirm that I have understood all sections of this form. I have read the entire form (5 pages). During the interview, the doctor, Mr./Ms. _____ explained to me the course of the scheduled PET scan and informed me of any risks specific to my case and of any potential complications which could result from them as well as of the advantages and disadvantages of the scheduled procedure compared with alternative methods available.

Ich bestätige hiermit, dass ich alle Bestandteile der Patientenaufklärung verstanden habe. Diesen Aufklärungsbogen (5 Seiten) habe ich vollständig gelesen. Im Aufklärungsgespräch mit Frau/Herrn Dr. ___ wurde ich über den Ablauf der geplanten PET, deren Risiken, Komplikationen und Nebenwirkungen in meinem speziellen Fall und über die Vor- und Nachteile der Alternativmethoden umfassend informiert.

I hereby deliberately waive a detailed explanation. However, I hereby confirm that the doctor whose patient I am instructed me regarding the necessity of a PET scan, its type and scope as well as the fact that this examination method is accompanied by certain risks.

Ich verzichte bewusst auf eine ausführliche Aufklärung. Ich bestätige hiermit allerdings, dass ich von dem behandelnden Arzt über die Erforderlichkeit der PET, deren Art und Umfang sowie über den Umstand, dass die Untersuchung Risiken birgt, informiert wurde.

I hereby confirm that I do not have any additional questions and do not need more time for consideration. I consent to the examination as proposed. I have answered the questions regarding my medical history (anamnesis) fully to the best of my knowledge.

Ich versichere, dass ich **keine weiteren Fragen** habe und **keine zusätzliche Bedenkzeit** benötige. **Ich stimme der vorgeschlagenen Untersuchung zu.** Die Fragen zu meiner Krankengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.

I confirm that I am capable of following the instructions given to me by my doctor.

Ich versichere, dass ich in der Lage bin, die ärztlichen Verhaltenshinweise zu befolgen.

I consent to my anonymised examination results being used for scientific research purposes.

Ich bin damit einverstanden, dass meine anonymisierten Untersuchungsergebnisse zur wissenschaftlichen Verwertung verwendet werden.

I agree that my copy of this explanatory form may be sent to the following e-mail address: Ich bin damit einverstanden, dass meine Kopie dieses Aufklärungsbogens an folgende E-Mail-Adresse gesendet wird:

_____ e-mail address [E-Mail-Adresse]

Place, Date, Time [Ort, Datum, Uhrzeit]

Signature of patient/legal guardian(s)
[Unterschrift Patient/in / Eltern?/ Betreuer / Vormund]

Copy/Kopie: received/erhalten
 waived/verzichtet

Signature Copy received/waived
[Unterschrift Kopie erhalten/verzichtet]

*If only one parent signs, then by so doing this parent declares that he/she has sole rights of custody or is acting with the consent of the other parent.

