

Patient Information for a PET/CT Examination with ⁶⁸Gallium PSMA

Dear patient,

Your physician has referred you for further diagnostic clarification of a prostate tumour or its metastases. An established substance is used, which, however, has not yet been approved for general application by the respective authorities and may therefore only be used within the context of a so-called "individual diagnostic treatment attempt". An improved and more detailed delimitation or depiction of afflicted tissue, in particular also outside of the prostate, is possible based on published data*. Even the smallest tissue metastases can be detected, which, thus far, could not be detected by established verification procedures.

For the examination, a small amount of gallium 68-labelled PSMA (⁶⁸Ga PSMA^{HBED-CC} in short: PSMA) is injected in the vein approximately 1 hour prior to the PET/CT scan. After the injection, the ⁶⁸Ga PSMA reaches the diseased tissue via the blood vessel system and accumulates significantly more at diseased cells than in normal tissue. The PSMA is labelled prior to the injection with a short-life radioactive substance (gallium 68) in order to observe and depict the distribution in the body. The physical half-life of gallium 68 is only 68 minutes. The accumulation location can be localised with the PET/CT scanner via the radiation from gallium 68, making it possible to depict the sought tissue. A CT examination is performed and ⁶⁸Ga PSMA images are automatically superimposed over the CT images and evaluated jointly (PET/CT) in order to ensure a secure allocation to known structures (lymph nodes, soft tissue). Found nidi can be precisely allocated to the respective structures with the PET.

Procedure

The patient does not have to undergo the examination on an empty stomach and may eat a small breakfast. The ⁶⁸Ga PSMA must be prepared on-site in cooperation with our team's radiochemists due to the short physical half-life of the substance. The manufacturing process is subject to strict quality controls; all previous quality controls have revealed no conspicuous results. The PSMA is injected into the vein approx. 60 minutes before the PET/CT examination. Concurrently, a diuretic is administered (20mg furosemide) in order to improve image quality; the diuretic also ensures a rapid excretion of the radiopharmaceutical from the body. You will be specifically informed about associated contraindications prior to the application. You will have to again empty your bladder immediately prior to the examination in the PET/CT scanner.

The patient lies on a special table in a ring that is open on both ends during the PET/CT imaging procedure as images of the patient's body are recorded continuously.

The only inconvenience of the examination is that you have to lie still (for approx. 20 minutes).

Possible risks and alternatives

The risks associated with participation in this examination are very low. Side effects (allergic reactions, nausea, vomiting etc.) due to the PSMA are not to be expected or have not yet been observed. The PSMA itself is not an X-ray contrast agent; intolerance in regard to the PSMA is therefore not to be expected. The examination with gallium PSMA does not exclude a possible known intolerance to X-ray contrast agent. Moreover, ⁶⁸Ga PSMA^{HBED-CC} is currently in a clinically prospective pharmaceutical study (www.clinicaltrials.gov: NCT02611882) in which pharmaceutical safety is consistently monitored; a quick response time is ensured in case of unexpected side effects.

Radiation exposure

Radiation exposure due to ⁶⁸Gallium PSMA^{HBED-CC} PET-CT is approximately 5mSv and thus falls within the same limit as typical radiological examinations (such as CT).

Patient statement:

I have been sufficiently informed about the usage and risks of the examination and give my consent to the examination.

- I agree to the, of course anonymous, usage of my examination data for scientific or statistical purposes as well as for technical presentation purposes.

Signature of patient

Signature/Name of clarifying physician

*Evaluation of Hybrid ⁶⁸Ga-PSMA Ligand PET/CT in 248 Patients with Biochemical Recurrence After Radical Prostatectomy. Eiber M, et al., J Nucl Med. 2015 May;56(5):668-74. doi: 10.2967/jnumed.115.154153. Epub 2015 Mar 19.

Anamnesis examination (NOT to be filled out by the patient):

Height:

Weight:

Tumour (histology, stadium, Gleason score):

Operation (when?):

PSA:

Radiotherapy (when?):

Hormone therapy?

Metformin?

CM - allergy?

TSH?

Creatinine?

Applied activity, tracer: _____ Mbq Uptake phase in min.: _____