

Patient information and declaration of consent for participation in the clinical trial

Evaluation of the diagnostic value of TOF¹-18F-FDG PET/CT in patients with suspected pancreatic cancer

Dear Patient!

We invite you to participate in the above mentioned clinical study. This will be explained in a detailed medical consultation.

Your participation in this clinical trial is voluntary. You can withdraw from the study at any time without giving reasons. Refusal to participate or early withdraw from this study will not adversely affect your medical care.

Clinical studies are necessary to obtain reliable new medical research results. However, an indispensable prerequisite for conducting a clinical trial is that you give your written consent to participate in this clinical trial. Please read the following text carefully as a supplement to the information with your study physician and do not hesitate to ask questions.

Please sign the declaration of consent only

- when you have fully understood the nature and procedure of the clinical trial,
- if you are willing to agree to participate, and
- if you are aware of your rights as a participant in this clinical trial.

The responsible ethics committee issued a favorable opinion on this clinical study, as well as on the patient information and declaration of consent.

1. What is the purpose of the clinical trial?

The purpose of this clinical study is to clarify whether a new imaging technique (time-of-flight reconstruction algorithm), 30min and 90min p.i. (=post injectionem, i.e., after intravenous administration of 18F-FDG) as well as a diagnostic CT of the abdomen with contrast medium and pancreas protocol as part of the routine PET/CT examination have a benefit in distinguishing malignant from benign lesions in the pancreas.

¹The „Time-of-Flight“ technology is a new image reproduction technology in PET/CT. Using Ultra High-Definition PET technology, the spatial resolution can be significantly improved (to 2 mm), and the sensitivity (TOF) can be increased by a factor of 3. Thus, even tiny lesions can be localized precisely.

2. How does the clinical trial work?

This clinical trial will be conducted at the Division of Nuclear Medicine, University Hospital of Radiology and will involve approximately 118 people in total.

Your participation in this clinical trial is expected to take 4 weeks.

During this clinical study at intervals of a maximum of 4 weeks, the following examinations will be performed: PET/CT-examination, surgery or fine needle puncture. If you *do not have* a fine needle puncture or surgery, you are automatically *excluded* from the study.

The following measures are carried out exclusively for study reasons:

Diagnostic CT of the abdomen with pancreas protocol with intravenous administration of a contrast medium containing iodine and oral (=through the mouth, i.e., for drinking) administration of 500 ml water as well as 30min and 90min post-injection images within the scope of the PET/CT-examination.

In the case of increased renal or decreased thyroid function parameters (TSH), or of a known contrast medium intolerance, a diagnostic CT will be performed *without* contrast medium.

3. What is the benefit of participating in the clinical trial?

It is possible that your participation in this clinical trial will not result in a direct benefit for your health. By carrying out images 30min and 90min post-injection, as well as a diagnostic CT of the abdomen with contrast medium and application of the TOF technique (carried out without patient contact) the interpretation of the FDG PET-CT images can be improved. The results of image interpretation will be compared with the results of the histopathological evaluation of the surgical specimen/biopsy.

These findings shall help to optimize the therapy options after completion of the study.

4. Are there any risks, complaints or side effects?

The measures of the study concerning the patient will be routinely carried out so that there are no additional risks due to the study.

The F18-FDG-PET-CT examination is based on the application of marked radioactive sugar, which is applied intravenously. This examination is connected to low exposure to radiation as well as the performance of the diagnostic CT of the abdomen (total approx. 18mSv). This is lower according to §12 AllgStrSchV as the maximum allowable annual dose for occupationally radiation exposed persons which should not exceed 50 mSv per year or a total dose of 100 mSv within 5 years.

The administration of an iodine-containing contrast medium can lead to incompatibilities and, very rarely to an allergic shock.

The operation (pancreatoduodenectomy) is performed routinely under general anesthesia. Postoperative pain and possible bleeding can be complications.

In rare cases, this can lead to infections.

The fine needle puncture is an invasive intervention in the body and is performed with the help of local anesthesia. The side effects that can be considered here are pain and bleeding.

5. Additional medication?

None.

6. Does participation in the clinical trial have any other impact on lifestyle and what obligations does it entail?

None.

7. What should be done when symptoms, side effects and/or injuries occur?

If any symptoms, side-effects or injuries occur in the course of the clinical trial, you must inform your physician, in the case of severe side effects immediately, if necessary by telephone (telephone numbers, etc. see below).

8. When will the clinical trial be terminated prematurely?

You can withdraw your willingness to participate and remove from the clinical trial at any time without giving any reasons and without any disadvantages for your further medical care.

Your study physician will immediately inform you of any new findings that may become known about this clinical trial, and that may be of significance to you. On this basis, you can then reconsider your decision to **continue** participating in this clinical trial

However, it is also possible that your study physician may decide to terminate your participation in the clinical trial prematurely without first obtaining your consent. The reasons for this could be:

- a) You cannot meet the requirements of the clinical trial;
- b) Your study physician has the impression that further participation in the clinical study is not in your interest.

9. How will the data collected in this trial be used?

Unless otherwise required by law, only study physicians and their staff have access to the confidential data in which you are named. These persons are bound by the duty of confidentiality.

The passing on of the data takes place exclusively for statistical purposes, and you are not named without exception. You will also not be mentioned by name in any publications of the data of this clinical study. You can revoke the transfer of your data at any time without giving reasons.

10. Are there any costs for the participants? Is there any cost reimbursement or remuneration?

Your participation in this clinical trial will not result in any additional costs; the study does not assume any remuneration and does not pay for the costs.

11. Possibility to discuss further questions:

If you have any further questions in connection with this clinical study, please do not hesitate to contact your study physician and his staff. Questions concerning your rights as a patient and participant in this clinical trial will also be answered.

12. Declaration of consent

Name of the patient in block letters:

Date of birth: Code:

I agree to participate in the clinical trial „evaluation of the diagnostic value of TOF-18F-FDG PET/CT in patients with suspected pancreatic cancer“. I have been informed in detail and comprehensibly by Mr./Mrs. about possible burdens and risks, as well as about the nature, significance, and scope of the clinical study and the resulting requirements for me. I have also read the text of this patient information and consent form, which has a total of 5 pages. Questions that arose were answered comprehensibly and sufficiently by the doctor. I've had plenty of time to make up my mind. I don't have any more questions right now.

I will comply with any medical orders required for the conduct of the clinical trial, but I reserve the right to terminate my voluntary participation at any time without prejudice to my continued medical care.

At the same time, I agree that my collected data within the framework of this clinical trial can be recorded. The competent authorities are allowed to inspect my personal disease data with the study physician to ensure the accuracy of the data recording.

The provisions of the Data Protection Act as amended are complied with.

I have received a copy of this patient information and consent form. The original remains with the study physician.

.....
(Date and signature of the patient)

.....
(Date, name, and signature of the responsible investigator)

(The patient receives a signed copy of the patient information and declaration of consent, the original remains in the study folder of the study physician.)