Information for study participation

National study for patients with small, non-hormone producing neuroendocrine tumors of the pancreas (PANDORA-2)

Introduction

Dear reader,

With this information letter we kindly like to ask you to participate in our national study about pancreatic neuroendocrine tumors. Participation is voluntary. You are receiving this letter because you were diagnosed with a small neuroendocrine tumor of the pancreas.

In this letter you can read what kind of research this concerns, what it means for you and what is expected of you if you decide to participate.

Are you interested?

- Please read this letter carefully.
- Ask questions of the researcher who provides you with this information.
- Talk to your partner, family, or friends about this study.

Would you like to participate? Please complete the form in the attachment.

1. General information

This study has been initiated by the Amsterdam UMC and is performed by doctors and researchers in different hospitals throughout the Netherlands. This study will collect information from patients with a small, non-hormone-producing neuroendocrine tumor of the pancreas. We will also conduct research using any remaining bodily material.

2. What is the aim of this study?

This study has 3 important aims:

1. National, coded data registration of patient and tumor characteristics (e.g. age, tumor type, size, location) for use in scientific research.
2. Identifying and validating new biomarkers. Biomarkers are specific tumor characteristics that help us understand tumor behavior. These biomarkers enable us to predict more accurately which tumors are likely to metastasize and which are not. With this knowledge, we can determine the most accurate treatment and follow-up plan for each individual patient.

3. What is the background of this study?

Neuroendocrine tumors of the pancreas are rare, only occurring in around 0.2-2/100.000 patients. There are many types of neuroendocrine tumors, some produce hormones and are called functional tumors. The majority however do not produce hormones and are therefore non-functional. The symptoms that patients experience from these tumors vary, with a small group of patients being symptom-free.

Currently, the only permanent solution for the tumor is extensive surgery, which can result in complications. Patients with a small non-functional tumors ≤2 cm are preferably followed through scans (MRI-scans/CT-scans/PET-scan) instead of an operation. This is possible because small tumors either do not grow or grow very slowly, and patients can therefore be spared the complications of surgery. Only if the tumor grows, or if (serious) complaints or discomfort arise, is surgery advised. However, if you have a strong preference for surgery, you can discuss this with your physician.

The previous PANDORA-1 study has taught us that small, non-functional tumors exhibit little growth and that active surveillance with scans is a safe option.

In this PANDORA-2 study, we aim to continue investigating the long-term safety of this treatment by gathering information from as many people as possible with a small neuroendocrine tumor who initially did not undergo surgery. We also want to improve care for the small group of people whose tumors do grow. We aim to do this by researching biomarkers. These biomarkers can help us predict tumor growth even more accurately. In the future, this will allow us to predict tumor behavior at an earlier moment, rather than having to detect growth on a scan when it has already happened. We are conducting this biomarker research in collaboration with the University Medical Center Utrecht.

4. What will happen if you participate in this study?

Your medical data relevant to neuroendocrine tumor research will be collected from your medical record and stored in a coded database. This data will be used for scientific research. Your name, date of birth, and address will not be included in this database.

Furthermore, a biopsy may have been taken to confirm the diagnosis of a neuroendocrine tumor. The remaining tissue will be used to study the biomarkers. This includes genetic analysis of the tumor tissue. This analysis will yield genetic information specific to the tumor, not hereditary genetic information. We will ask you for your separate consent to participate in the PANDORA biomarker study on the consent form.

5. What will participation mean for you?

You will receive follow-up according to the PANDORA-2 schedule, which consists of 6 check-ups spread over 10 years, unless otherwise agreed with your healthcare provider.

You will not directly benefit from participating in this study. Your participation can, however, contribute to increased knowledge about pancreatic neuroendocrine tumors and thus improve the quality of care. Participation does not cost you any additional time.

6. If you do not want to participate or want to stop participating in the study.

Participation in the study is entirely voluntary. You may also decide to stop participating during the study. You do not have to explain your reasons for stopping. However, you must inform the researcher immediately. The data collected up to that point will be used for the study.

7. What do we do with your information?

By participating in this study, you also consent to the collection, use, and storage of your data.

Why do we collect, use, and store your data?

We collect, use, and store your data to answer the questions in this study.
We intend to publish the results of the study.

How do we protect your privacy?

To protect your privacy, we assign a code to your data and bodily material. Only this code will be placed on all your data and bodily material.

The data directly referring to you will then no longer be used. A protected file called the 'key' can link the data to your name, this key will be stored in a secure location at the local research institution. Only the coordinating researcher and the researcher involved at your hospital have access to this key. Whenever we process or share your data, we only use that code. No one can trace information back to you in reports and publications about the study.

To conduct the biomarker research, the tumor tissue is collected in a single location: the UMC Utrecht. To get the tissue to this location, we need to request it from the hospital where the biopsy was taken. To request the tissue from the correct person, we need your name and date of birth. The hospital where you were treated will securely share this information with the researcher conducting

the biomarker research. This researcher will then securely share this information with the department where your tissue is stored, so they can retrieve the tissue.

How long do we retain your data?

We retain your data for 15 years at the research location.

Can we use your data for other research?

After this study, your data may also be relevant to other scientific research on pancreatic neuroendocrine tumors. For this purpose, your data will be retained for 15 years at the research site. You can give your consent for this on the consent form. If you do not consent, you can still participate in this study.

Can you withdraw your consent for the use of your data?

You can withdraw your consent for the use of your data at any time. This applies to the use of your data both in this study and in other research. However, if you withdraw your consent and researchers have already used your data for research, they may still use that data.

May we contact you again for a follow-up study after this research?

Once this study is completed, we may conduct a follow-up study. In that case, we would like to contact you to ask if you would like to participate again. You can indicate on the consent form whether you consent to this.

Would you like to know more about your privacy?

You may wish to receive an electronic copy of your data used in the study. This is possible. You can request this from the researcher.

Would you like to know more about your rights regarding the processing of personal data? Then please visit https://www.autoriteitpersoonsgegevens.nl/en/themes/basic-gdpr/privacy-and-personal-data

Do you have any questions about your rights? Or do you have a complaint about your privacy? Please contact the person responsible for processing your personal data.

If you have any complaints about your privacy, we recommend that you first discuss them with the research team. You can also contact your institution's Data Protection Officer. Or you can file a complaint with the Dutch Data Protection Authority.

Where can I find more information about the study?

You can find more information about the study on the following websites:

https://dpcg.nl/studie/pandora-2/

8. Do you have any questions?

This study was reviewed by the non-WMO review committee of the Amsterdam UMC. According to this committee, this study does not fall under the Medical Research Involving Human Subjects Act (WMO). If you have any questions about this study, please contact the researcher or your treating physician. If you have any complaints about this study, you can discuss them with the coordinating researcher or your treating physician. If you would prefer not to discuss with them, you can contact your hospital's complaints committee.

Thank you for your attention.

Contact information:

If you have any questions about the PANDORA-2 study, please contact the coordinating physician-researcher:

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Questions regarding the biomarker research:

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Attachment: Participant consent form

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- I have read the information letter. I was also able to ask questions. My questions were answered satisfactorily. I had enough time to decide whether to participate.
- I understand that participation is voluntary. I also understand that I can decide at any time not to participate or to withdraw from the study. I don't have to give a reason for this.
- I give permission to the research team members to view my medical file and to copy, store, and use the coded data (without personal information such as name or patient number) from my file required for this study in the manner and for the purposes stated in the information letter.
- I give permission for the retrieval of my (medical) data necessary for conducting this study from my medical file at the hospital where I am being treated.
- I give permission to share my name, date of birth, phone number, and email address with the coordinating researcher so they can contact me if there are any problems. This information will be coded and stored securely.
- I O do O do not
  give permission to retain my data for 15 years after this study. This data will then be kept for future research, as stated in the information letter.
- I O do O do not
  give permission to contact me again after this study for a follow-up study.
- I want to participate in this study.
  O Yes
  O No

<u>Consent biomarkers (if applicable)</u>

- If tissue has been obtained and any residual material remains after use, I give permission for it to be used for biomarker research.
- I give permission to securely share my name, date of birth, and this consent form with the researcher conducting the biomarker study, solely for the purpose of requesting the appropriate tissue from the hospital where I was treated. This information will be stored securely.

- I give permission to securely share my name, date of birth, and this consent form by the researcher conducting the biomarker study with the department where my remaining tissue is stored.
- I O do O do not
  give permission to perform a genetic analysis on my tumor tissue as part of this biomarker research.
- I want to participate in this biomarker research.
  O Yes
  O No

Name participant:

Signature: Date : __ / __ / __

I declare that I have fully informed this participant about the aforementioned study.

If any information becomes known during the study that could affect the participant's consent, I will inform them in a timely manner.

Name researcher:

Signature: Date: __ / __ / __

The participant will receive a full information letter, together with a copy of the signed consent form.

Study number: _____ Hospital: _____

The study number will be assigned by the research team after you have returned the consent form.