

## Patient information folder

### PANDORA-2

#### PAncreatic NeuroenDOcrine Tumor Patients

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

Dear sir/madam,

We kindly like to ask you to participate in our national study about pancreatic neuroendocrine tumors. You are not obligated to participate. You are receiving this letter because you were diagnosed with a small neuroendocrine tumor of the pancreas. Before you decide to participate in this study, it is important to read the information below.

#### 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. The Medical Ethics Committee has approved this study.

#### 2. Background Information

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.

Currently, the only permanent solution for the tumor is extensive surgery, which can result in complications. Patients with a small non-functional tumors  $\leq 2$  cm are preferably followed through scans (MRI-scans/CT-scans/PET-scan) instead of an operation. 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. Furthermore, it also revealed that patients were having trouble with following the frequent check-ups. Because of that, we started the PANDORA-2 study. In this study we have halved the amount of radiological check-ups during follow-up. At the same time we will send you questionnaires to see what kind of effect this has on your quality of life. Also we will be offering active support during the follow-up to a portion of participants.

#### 3. Wat is the aim of this study?

This study has 3 important aims:

- 1) Simplifying the current follow-up protocol by lowering the frequency of radiological check-ups without losing excellent tumor control and contributing to a better quality of life.
- 2) To collect patient and tumor characteristics on a national scale for scientific research on neuroendocrine tumors.
- 3) Developing and implementing a method to provide supportive care to patients during long-term follow-up and improve the quality of life.

#### **4. How is this study performed?**

Your medical data which is relevant for research on neuroendocrine tumors, will be collected from your medical file and saved in a database. If you give us permission for the quality of life questionnaires, you will receive these twice a year via the postal service. It only takes 10 minutes to fill out the questionnaires. You will receive them for the duration of 4 years. You are not obligated to fill these out. For the use of the questionnaires, your name and address will be kept in a separated, protected database. Only the person sending the questionnaires has access.

#### **5. Does anything change in my regular treatment?**

You will receive 6 radiological check-ups instead of 12.

#### **6. Wat are the pro's and con's?**

The pros are that you will help in improve the quality of care for patients with this rare tumor. The cons are that it will cost you time to fill out the quality of life questionnaires (only if you accept this option).

#### **7. What if I want to end my participation?**

You may end your participation in this study at all times, you do not have to give a reason. You do however, have to contact the researcher immediately if you wish to stop your participation (via email). Your data that has already been processed will be used for research. All other data will be destroyed, if that is your preference.

#### **8. Use and storage of personal information**

For this study, your medical data will be collected and stored in a database. To protect your privacy, your personal data will be given a code. Your name and any other identifiable data will be kept out of the database. A protected file called the 'key' can link the data to your name. It is saved in a protected area in the Amsterdam UMC and is only accessible by the researcher.

Your data is saved for 15 years at the Amsterdam UMC. It could be important for future medical research on the subject of neuroendocrine tumors. You can give separate permission on the consent form, for use of your coded data by others

#### **9. Do you have any questions?**

If you have any questions you can contact the researcher or your physician. If you have any complaints regarding this study, you can discuss this with either the researcher or you physician. If you do not wish to do so, you can also contact the internal complains commission of the hospital.

#### **Contact information**

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