# Small pancreatic neuroendocrine tumors

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A conservative approach, rather than surgical resection, is safe for non-functioning grade 1 and 2 pancreatic neuroendocrine tumors

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON22819

**Bron**
NTR

**Verkorte titel**
PANDORA

**Aandoening**

Pancreatic neuroendocrine tumors

Neuroendocriene tumoren van de alvleesklier

### Ondersteuning

**Primaire sponsor:** None
**Overige ondersteuning:** C.G. Genc received a non-restricted fund for her PhD from Ipsen.

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Tumor progression

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale: pancreatic neuroendocrine tumors (pNET) are more often diagnosed incidentally due to the use of better imaging techniques. Surgical resection is the only curative treatment and long term follow-up indicates a survival benefit for patients who underwent primary resection. However, pancreatic resections are associated with serious postoperative morbidity. In addition, recent literature shows that incidentally found pNET have a significant smaller size and are more commonly associated with lower tumor stages. Progression or tumor growth in small incidentally found non-functioning pNET seems minimal. Therefore, the European Neuroendocrine Tumor Society (ENETS) has updated their guidelines; surveillance is now recommended for patients with non-functional pNET <2cm. Although this approach seems safe, long term follow-up data are needed to guarantee the safety of this policy.

Objective: To monitor long term effects of a non-operative management of small pNETs.

Study design: A prospective, multicentre, cohort in collaboration with all Dutch Pancreatic Cancer Group (DPCG) affiliated centers that treat patients with pNET.

Study population: patients diagnosed with a pNET <2cm.

Endpoints: Tumor progression and survival will be the primary outcomes. In addition, patients who do undergo a resection despite the guideline will be observed. The reasons to deviate from the initial therapy will be investigated. A secondary outcome will be the quality of life of all patients that are diagnosed with a pNET <2cm, regardless of received therapy.

### Doel van het onderzoek

A conservative approach, rather than surgical resection, is safe for non-functioning grade 1 and 2 pancreatic neuroendocrine tumors <2cm.

### Onderzoeksopzet

Wait-and-see protocol

- year 1: 3, 6, 9, 12 months

- year 2: 18, 24 months

- year 3: 30 36 months

- year 3-10: every 12 months

After surgical resection:

- year 1: 6 and 12 months

- year 2-5: every 12 months

**Onderzoeksproduct en/of interventie**

No interventions, since patients will be treated according to the international 2016 ENETS guidelines.

# Contactpersonen

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Diagnosed with pancreatic NET on at least 2 imaging modalities (pathology is not necessary, only in doubt)

- No distant metastases

- Patients >18 years

- Able to read and write in Dutch/English

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Hereditary syndromes

- Functioning pNET (insulinoma, gastrinoma etc)

- pNET grade 3 according to 2010/2017 WHO grading system

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-01-2017 |
| Aantal proefpersonen: | 100 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 06-09-2017 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL6510 |
| NTR-old | NTR6698 |
| Ander register | AMC ziekenhuis : W16_242 # 16.283 |

# Resultaten