Small pancreatic neuroendocrine tumors

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22819

Source
NTR

Brief title
PANDORA

Health condition

Pancreatic neuroendocrine tumors

Neuroendocriene tumoren van de alvleesklier

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: C.G. Genc received a non-restricted fund for her PhD from Ipsen.

Intervention

Outcome measures

Primary outcome

Tumor progression

Secondary outcome

Surgical resection rate

Reasons to resect

Quality of Life

Survival

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- Hereditary syndromes

- Functioning pNET (insulinoma, gastrinoma etc)

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2017
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-09-2017

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6510
NTR-old	NTR6698
Other	AMC ziekenhuis : W16_242 # 16.283

Study results