NETest in patients with resected pancreatic neuroendocrine tumor

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neoplastic and ectopic endocrinopathies
Study type	Observational invasive

Summary

ID

NL-OMON44092

Source
ToetsingOnline

Brief title
NETest in patients with resected pancreatic neuroendocrine tumor

Condition

- Neoplastic and ectopic endocrinopathies
- Endocrine neoplasms malignant and unspecified

Synonym
pancreatic neuroendocrine tumor, pNET

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ipsen Pharmaceuticals

Intervention

Keyword: Gene transcript analysis, NETest, Pancreatic neuroendocrine tumor

Outcome measures

Primary outcome

The primary outcome is the outcome of the NETest of the patients in the three different groups. A NET score (0-100%) is obtained from algorithmic analyses of PCR data using MATLAB (R2011a, Mathworks, Natick, MA, USA) . A value >= 20% will be considered as a positive test. Scores randing from 0-20% = negative (no evidence of tumor disease activity: NET-negative).

Scores ranging from 20-43% are considered *low activity* (NET-positive).

Scores ranging from 44-100% are considered *high activity* (NET-positive).

Secondary outcome

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Study description

Background summary

Pancreatic neuroendocrine tumors (pNET) a rare but in the recent years, the incidence is raising. Based on the overproduction of hormones, clinical syndromes may occur and pNET can be divided in functioning and non-functioning pNET. Although most pNET are non-functioning tumor, these tumors may produce hormones as well. These hormones can be measured in the blood and therefore they can be used as tumor markers. The best known tumor marker is chromogranin A (CgA). The sensitivity of CgA varied from 24-88%. In patients with an high tumor load, the diagnostic accuracy of CgA becomes better. In the cohort of resected non-functioning pNET (NF-pNET) of the Academic Medical Center (AMC), Amsterdam, the sensitivity and specificity for the detection of metastases after curative resection for CgA is respectively 67% and 68%. The diagnostic accuracy of CgA is moderate, since CgA is false positive in other conditions as well. A elevated value of CgA without evidence of recurrent disease on radiological imaging, may cause a lot anxiety in the patients.

In case of recurrent disease, multiple treatment options are available such as local resection or radiofrequency ablation (RFA) 9 of the metastases, chemotherapy, somatostatin analogues, peptide receptor radionuclide therapy and new agents such as Everolimus and Sunitinib. Early detection of recurrent disease and therefore early start of further treatment are the main goal during follow up after curative resection for pNET.

A complete and uniform follow up program is not yet available. The current program include CgA determination and radiological examinations. Radiological examination often consist of an CT/MRI on a yearly basis. However, octreotide scintigraphy or 68Galium PET are also available. Since CgA has a moderate accuracy and radiological imaging are less sensitive in small lesions, the ideal follow up program is still on debate.

Modlin et al developed a new diagnostic test, the NETest. This is a multianalyte PCR blood test, specific for neuroendocrine tumors. With a sensitivity and specificity of both 92.8% for diagnosis, the NETest seems promising. The NETest may be used during follow up in the early detection of recurrent disease after curative resection for pNET. Furthermore, in patients with (microscopically) positive resection margins, possible present residual tumor can be demonstrated. An early treatment or adjuvant treatment can be started in these patients.

Study objective

The aim of this study is to investigate if the NETest is useful in the follow up program after curative resection in patients with pNET. Therefore the diagnostic accuracy of the NETest in resected patients with pNET will be analysed.

The study is based on the following hypothesis:
H0: the NETest has a better diagnostic accuracy for the detection of recurrent disease or tumor residual after a curative resection for pNET in comparison with the current follow up program.

The study is intended to analyse three groups and we will test the following assumptions:
1. Patients with pNET have a negative NETest after their curative R0 resection
2. Patients with pNET have a positive NETest if they developed recurrent disease or metastases after their R0 resection.
3. Patients with pNET have a positive NETest after their R1/R2 resection

A R0 resection is defined as negative resection margins. R1 resection is defined as the presence of tumor cells within 1 mm of the resection margin. R2 resection is defined as macroscopic positive resection margins.

Study design

The study is an prospective cohort study.

Study burden and risks

The blood samples will be obtained during the standard laboratory tests in the outpatients clinic. There may be risk of infection of the puncture site or an hematoma. The burden of the laboratory test will not be higher by the extra blood samples.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- the patient is 18 years of older
- the patient is primarily treated with a surgical resection for pNET
- the patients is in the follow up program of the Academic Medical Center of Amsterdam (AMC)
- the patients is able to understand the given information

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- the patient is younger than 18 years
- the patient is not in the follow up program of the AMC
- the patient had metastatic disease at the time of the primary tumor
- the patient is not able to give informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	07-04-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL50925.018.15