Hepatic NET metastasis embolization biomarker evaluation

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The purpose of this study is to evaluate the effect of local ablative treatment or embolisation or SIRT on circulating NET transcripts (PCR score or NETtest). In particular, the variation of circulating NET transcripts will be correlated to NET...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON44840

Source
ToetsingOnline

Brief title
Hepatic NET metastasis embolization biomarker evaluation

Condition

- Endocrine neoplasms malignant and unspecified

Synonym
Neuro endocrine tumor

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: shipment en bepaling worden betaald door Yale University USA

Intervention

Keyword: biomarker, GEP-NET, NET

Outcome measures

Primary outcome

Effect of hepatic metastatic embolization (HAE/SIRT) on PCR score

Secondary outcome

1) Determine whether blood PCR score correlates with metastasis burden

2) Determine whether ablation efficacy and PCR score correlate with assessment

of tumor anatomical burden post-ablative imaging

3) Determine whether embolization/SIRT efficacy and PCR score correlate with

tumor assessment anatomical burden post embolisation

4) Correlate residual tumor burden using functional tumor imaging with PCR

score.

5) Evaluate stability/progression of tumor post ablation using PCR score vs.

patient parameters and imaging.

6) Comparison of plasma CgA measurements with the PCR score, for the same.

Study description

Background summary

Biomarker-based tools that can accurately predict gastroenteropancreatic neuroendocrine tumor (GEP-NET) treatment response and tumor recurrence are currently not available. Circulating biomarkers that are associated with GEP-NETs are limited to measurements of plasma chromogranin A (CgA). Modlin et al. have developed a PCR-based tool to quantitate (score) the circulating GEP-NET molecular signature (*liquid* biopsy) with high sensitivity and specificity21. This signature can identify all types of GEP-NETs including small, non-metastatic tumors, is significantly reduced after tumor debulking

and is absent following surgical *cure*. Their observations indicate the score is elevated before tumor recurrence is detected by RECIST criteria. Current NET treatment protocols are associated with tumor recurrence (progression free survival) ranging from 5 to 18 months. The majority of patients will experience a relapse within 18 months irrespective of the treatment approach and most of these patients develop liver metastasis only, who eventually will undergo a local ablative therapy like Radiofrequency Ablation (RFA), Microwave Ablation (MWA), or a (bland) liver embolization (TAE or SIRT). We hypothesize that a PCR measurement of circulating NET mRNA can accurately predict tumor response after local minimal invasive image guided treatment (RFA or MWA), or liverembolisation . This biomarker protocol seeks to test this hypothesis and evaluate this with the golden standard: CT scan.

Study objective

The purpose of this study is to evaluate the effect of local ablative treatment or embolisation or SIRT on circulating NET transcripts (PCR score or NETtest). In particular, the variation of circulating NET transcripts will be correlated to NET recurrence to test whether this analysis may constitute an early predictive marker of disease relapse.

Study design

Blood sampling schedule in 30 patients
• Whole blood will be collected at baseline (defined as prior to SIRT/embolisation/ablative moment); three base-line bloods.
• Blood samples before and 15 mins after each embolic or ablative event during the course of the procedure and day 5.
• Whole blood collected at each patient visit for the duration of study (defined as time when cancer progression is detected on imaging).
• Serum for CgA analysis will be taken at the same time points as the biomarker.

Intervention

Blood sampling schedule
• Whole blood will be collected at baseline (defined as prior to SIRT/embolisation/ablative moment); three base-line bloods.
• Blood samples before and 15 mins after each embolic or ablative event during the course of the procedure and day 5.
• Whole blood collected at each patient visit for the duration of study (defined as time when cancer progression is detected on imaging).
• Serum for CgA analysis will be taken at the same time points as the biomarker.

Study burden and risks

no risks associated with participation, no benefits associated with the study.

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

• >= 18 years old with metastatic well differentiated neuroendocrine tumor of gastro-enteropancreatic origin who will undergo a local ablative treatment or HAE/SIRT .
• Patients have measurable disease
• WHO performance status 0-2
• Life expectancy more than 3 months
• Use of the standard embolization/RFA NET-NKI protocol

Exclusion criteria

1. Known history of HIV seropositivity.
2. contraindication for liverembolisation, RFA/MWA or SIRT

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-04-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	06-01-2016
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	12-10-2017
Application type:	Amendment
Review commission:	METC NedMec

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	NL52942.031.15