11C-MET PET(/CT) vs 18F-FDG PET(/CT) in the follow-up of differentiated thyroid cancer*

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- Objective (Study) 1.To evaluate the clinical performance of MET PET during rhTSH stimulation and to compare the results of this MET PET with the clinical rhTSH stimulated FDG PET in patients with negative post-treatment 131I-whole body scan (WBS)...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thyroid gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON32909

Source
ToetsingOnline

Brief title
11C-MET PET(/CT) in DTC

Condition

- Thyroid gland disorders

Synonym
differentiated thyroid carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: aanvraag subsidie loopt

Intervention

Keyword: 11C- methionine, 18F-FDG, Differentiated thyroid cancer, Positron emission tomography

Outcome measures

Primary outcome

A qualitative and semi-quantitative (standardized uptake values (SUVs)) reading of all the PET studies will be performed. Comparison with data derived from clinical CT imaging data, and where feasible histological or cytological confirmation, will take place.

Ojective/Study 1: the results of 11C-MET PET will be compared with the clinical FDG PET

Objective/Study 2: the results of 11C-MET PET will be compared with the clinical FDG PET

The results of both PET scan will also be compared with the (diagnostic and) post-treatment 131I-WBS.

Secondary outcome

Premature termination of the study will be only if interim analysis after 15 and 10 evaluable scans for study/objective 1 and study/objective 2, respectively, showed negative or undoubtedly results for the 11C-MET PET compared to the clinical FDG PET.

Study description

Background summary

Although FDG PET(/CT), under TSH stimulation, is now considered as a valuable, established diagnostic imaging tool in the follow-up of 131I-negative patients for the detection of recurrences or metastases, the interest for new tracers and improvement of diagnostic tools in thyroid cancer is growing. Another target for metabolic tumor imaging is the increased protein metabolism and transport in cancer cells, to which radiolabeled amino acids can be applied. Amino acid transport is generally increased in malignant tissue, which could be associated with specific cell surface changes in transformed cells. The process of malignant transformation requires in general that cells acquire and use nutrients efficiently for energy, protein synthesis and cell division. Two major steps are involved in protein metabolism including increased amino acid transport and protein synthesis. It is imaginable that thyroid cancer could sufficiently concentrate amino acids due to its protein synthesis (e.g. thyroglobulin) and the often slowly progressive character in the well-differentiated tumors (e.g. Hurthlecell carcinoma).

The general feasibility of amino acid imaging with C-11 methionine (MET) PET under TSH suppression in differentiated thyroid cancer (DTC) has been shown (Phan et al, in press NMC). Interesting finding in the study of Phan et al. was the complementary uptake of MET and FDG in 25% of the patients. It has been hypothesized that this finding might be explained by the degree of tissue dedifferentiation. Hürthlecell carcinoma are known to be less radioiodine-avid compared to the well-differentiated papillary and follicular carcinoma or can be even non-iodine or non-FDG avid. For this group of patients MET PET might be of complementary value.

In-vitro study in the rat thyroid cells has suggested that the TSH level does not influence the amino acid uptake. However, no clinical intra-individually comparative studies between 18F-FDG PET and 11C-MET PET during (rh)TSH stimulation are available. It would be of interest to evaluate the diagnostic yield of MET PET scans under (recombinant human, rh)TSH stimulation and to compare these results with TSH stimulated FDG PET.

Study objective

- Objective (Study) 1.To evaluate the clinical performance of MET PET during rhTSH stimulation and to compare the results of this MET PET with the clinical rhTSH stimulated FDG PET in patients with negative post-treatment 131I-whole body scan (WBS) and elevated serum thyroglobulin (Tg(on) > 5.0 ng/nl).

- Objective (Study) 2. To evaluate the (complementary) value of (rh)TSH stimulated MET PET in patients with persistent or recurrent Hürthlecell

carcinoma in the post-ablation phase and during follow-up.

Study design

The Department of Internal Medicine * Endocrinology at the UMCG is the largest treatment center for thyroid cancer in the Netherlands. Since 1978 more than 650 patients have been treated for thyroid cancer. The materials and data of these patients are collected in a large database. The median follow-up duration is 11 years (range 1-24 years). Approximately 30-40 patients with DTC are referred to the UMCG for treatment annually. These patients are seen regularly at the outpatient clinic for follow-up. Difficult cases are discussed on a regular base in a multidisciplinary panel consisting of nuclear medicine physicians, endocrinologists and surgeons.
Patients for these pilot studies are firstly seen by their endocrinologist at the out-patient clinic for follow-up. In case patients fulfill the inclusion criteria described below, they will be referred to the department of Nuclear Medicine and Molecular Imaging (NMMI) for PET scanning as part of clinical patient care. The duration of these pilot studies is estimated to be 2-3 years.

Study 1: this pilot study evaluates the clinical performance of MET PET during rhTSH stimulation and to compare the results of the rhTSH stimulated MET PET with the standard rhTSH stimulated FDG PET in patients with negative post-treatment 131-I scans and elevated serum thyroglobulin (Tg).

Study 2: this pilot study evaluates the (complementary) value of MET PET in patients with persistent or recurrent Hürthlecell carcinoma in the post-ablation phase and during follow-up.

Study burden and risks

The patient will remain in fasting condition for at least 6 hours prior the 11C-MET PET, however is allowed to drink water and take his medication. At the time planned 7 MBq/kg 11C-methionine is injected via an intravenous canula inserted in a vein of a lower forearm. Twenty minutes post-injection of 11C-MET injection the patient will be positioned in the scanner and a *standard* PET study will be performed in whole body The whole procedure will take appoximately 90 minutes of which approximately 60 minutes will be spent in the camera. If possible, the 11C-MET PET and the clinical FDG PET will be combined on the same day. Patients will be asked to lay quietly during the scanning procedure.
The effective dose has been calculated at 0.0052 mSv/MBq for 11C-MET. The radiation dose is 2.9 mSv for a patient weighing 80 kg (7 MBq/kg) for the MET PET which complies with category IIb, ICRP-62. According to the RIVM the annual background from natural radiation in the Netherlands is 1.7 mSv. No adverse effect events are to be expected during the PET scanning. The physical discomfort during the scanning procedure is minimal.

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

Study 1
- > 18 years old
- Total thyroidectomy
- Negative post-treatment 131I-WBS with elevated Tg(on) (>5.0 ng/ml)
- Signed informed consent ;Study 2
- > 18 years old
- Total thyroidectomy
- Patients with persistent or recurrent Hürthlecell carcinoma in post-ablation phase or during follow-up
- Signed informed consent

Exclusion criteria

Both studies:
- Pregnancy
- Patients with any signs of neurological or psychiatric disorders that will preclude him/her from expressing her/his own free will

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):	22-07-2019
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL24825.042.08