11C-Methionin (MET) PET vs 18F-FDG PET in the follow-up of differentiated thyroid cancer.

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1. To evaluate 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...

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

Samenvatting

ID

NL-OMON24584

Bron
Nationaal Trial Register

Verkorte titel
MET PET vs FDG PET in DTC

Aandoening

patients with negative post treatment 131I-whole body scan and elevated serum thyroglobulin and patients with persistent or recurrent Hürthlecell carcinoma in the post-ablation phase and during folluw-up.

Ondersteuning

Primaire sponsor: no sponsor
Overige ondersteuning: no funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Objective/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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

1. To evaluate 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);

2. To evaluate the (complementary) value of MET PET in patients with persistent or recurrent Hürthlecell carcinoma in the post-ablation phase and during follow-up.

Onderzoeksopzet

No additional time point. 11C-MET PET scan will be combined with 18 FDG PET scan.

Onderzoeksproduct en/of interventie

11C-MET PET scan.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Objective (study) 1:

1. > 18 years old;

2. Total thyroidectomy;

3. Negative post-treatment 131I-WBS with elevated Tg(on) (>5.0 ng.ml);

4. Signed informed consent.

Objective (study) 2:

1. > 18 years old;

2. Total thyroidectomy;

3. Patients with persistent or recurrent Hürthlecell carcinoma in post-ablation phase or during follow-up;

4. Signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Both objectives/studies:

1. Pregnancy;

2. Patients with any signs of neurological or psychiatric disorders that will preclude him/her from expressing her/his own free will.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-01-2009
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-08-2009
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	NL1827
NTR-old	NTR1937
Ander register	METC UMC Groningen : 2008/231
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A