

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

No registrations found.

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

Summary

ID

NL-OMON24584

Source

Nationaal Trial Register

Brief title

MET PET vs FDG PET in DTC

Health condition

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 follow-up.

Sponsors and support

Primary sponsor: no sponsor

Source(s) of monetary or material Support: no funding

Intervention

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.

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.

Secondary outcome

No secondary outcomes.

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. Hurthlecell 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

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

Study design

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

Intervention

11C-MET PET scan.

Contacts

Public

University Medical Center Groningen
Div Endocrinology
PO Box 30 001
T.P. Links
Groningen 9700 RB
The Netherlands
+31 (0)50 3613962/+31 (0)50 3616161

Scientific

University Medical Center Groningen
Div Endocrinology
PO Box 30 001
T.P. Links
Groningen 9700 RB
The Netherlands
+31 (0)50 3613962/+31 (0)50 3616161

Eligibility criteria

Inclusion criteria

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 Hürthle cell carcinoma in post-ablation phase or during follow-up;
4. Signed informed consent.

Exclusion criteria

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.

Study design

Design

| | |
|---------------------|----------------------------|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

Recruitment

| | |
|---------------------------|-------------|
| NL | |
| Recruitment status: | Recruiting |
| Start date (anticipated): | 09-01-2009 |
| Enrollment: | 25 |
| Type: | Anticipated |

Ethics review

| | |
|-------------------|------------------|
| Positive opinion | |
| Date: | 06-08-2009 |
| 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 | NL1827 |

Register

NTR-old

Other

ISRCTN

ID

NTR1937

METC UMC Groningen : 2008/231

ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A