

Improving the diagnostic strategy of patients with recurrent differentiated thyroid cancer with PET/CT.

No registrations found.

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

Summary

ID

NL-OMON27626

Source

Nationaal Trial Register

Brief title

THYROPET

Health condition

Differentiated thyroid cancer

I-124 PET/CT

FDG PET/CT

Sponsors and support

Primary sponsor: The Netherlands Cancer Institute - Antoni van Leeuwenhoek hospital

Source(s) of monetary or material Support: KWF - The Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

The number of futile high-dose 131I treatments that could have been avoided by

implementation of pre-therapy imaging based on result of post-therapy scintigraphy.

Secondary outcome

1. Synchronised QA/QC of 124I-PET in the Netherlands;
2. Correlations of 124I-PET and FDG-PET with histopathological parameters and Tg;
3. Correlation between 124I-PET findings during rhTSH and withdrawal combined with LID.

Study description

Background summary

After initial treatment of DTC patients are followed biochemically by thyroglobulin to detect possible recurrence. Nowadays patients are treated blindly with high dose 131I. When recurrence is suspected a whole body scintigraphy is made, after blind administration of high dose, 'therapeutic', 131I to diagnose and treat recurrence and metastatic disease. In up to 50% this strategy can be considered to be futile because they had a negative post-therapeutic whole body scan and/or no objective therapy effect. 124I in combination with whole body PET became recently available for use in the follow-up of DTC. This could make it possible to more accurately re-stage patients in a whole body procedure, perform dosimetry for subsequent 131I therapy and predict the outcome of the treatment before the actual treatment with 131I. Additionally, recurrent DTC lesions that do not accumulate iodine can be re-staged without the futile treatment with 131I. FDG-PET is able to detect these lesions. The value of FDG-PET before 131I treatment however has not been tested.

The combination of these two diagnostic tools, 124I-PET and FDG-PET, has a potential to allow earlier and better restaging and selection for treatment.

The objective is to evaluate the value of combined imaging with 124I-PET and FDG PET in the prevention of futile treatment with high dose 131I.

Multicenter prospective observational cohort study.

Study objective

N/A

Study design

N/A

Intervention

A combination of I-124 PET/CT and FDG PET/CT to firstly detect the recurrence and secondly assess its biological behavior.

Contacts

Public

Huispost nummer G04.228

UMC Utrecht

Postbus 85500
J.W. Kist
Utrecht 3508 GA
The Netherlands
+31 (0)6 41853004

Scientific

Huispost nummer G04.228

UMC Utrecht

Postbus 85500
J.W. Kist
Utrecht 3508 GA
The Netherlands
+31 (0)6 41853004

Eligibility criteria

Inclusion criteria

1. Patients with a history of differentiated thyroid cancer;
2. After complete thyroidectomy and ablation of functional remnants with ¹³¹I;
3. Planned for blind high dose ¹³¹I treatment based on biochemically suspected recurrence, defined as a Tg-level above 2.0 ng/ml;
4. Ultrasonography of the neck performed < 2 months prior to inclusion.

Exclusion criteria

1. Age < 18 years;
2. Pregnancy;
3. Incapacitated subjects;
4. Contrast enhanced CT performed < 4 months prior to inclusion;
5. I-131 therapy performed < 12 months prior to inclusion;
6. Indication for other therapy modality (ie. surgery in case of a positive ultrasonography, radiotherapy, embolization or chemotherapy).

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:	Suspended
Start date (anticipated):	01-09-2012
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion	
Date:	10-07-2012

Application type:

First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38034

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3371
NTR-old	NTR3519
CCMO	NL37266.031.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38034

Study results

Summary results

N/A