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

Gepubliceerd: 10-07-2012 Laatst bijgewerkt: 19-03-2025

N/A

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

Samenvatting

ID

NL-OMON27626

Bron
Nationaal Trial Register

Verkorte titel
THYROPET

Aandoening

Differentiated thyroid cancer
I-124 PET/CT
FDG PET/CT

Ondersteuning

Primaire sponsor: The Netherlands Cancer Institute - Antoni van Leeuwenhoek hospital
Overige ondersteuning: KWF - The Dutch Cancer Society

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 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.

Doel van het onderzoek

N/A

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

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 tijdelijk gestopt
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-07-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38034
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A