Recurrent differentiated thyroid cancer: towards personalized treatment based on evaluation of tumor characteristics with PET

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

Summary

ID

NL-OMON38034

Source
ToetsingOnline

Brief title
THYROPET

Condition

- Thyroid gland disorders
- Endocrine neoplasms malignant and unspecified

Synonym
Differentiated tyroid carcinoma, thyroid cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Cyclotron BV, producent van radionucliden (sponsor jodium-124),KWF grant

Intervention

Keyword: FDG PET, Functional imaging, Iodine-124 PET, Thyroid cancer

Outcome measures

Primary outcome

- The number of futile 131I treatments that can be avoided using this imaging

strategy.

Secondary outcome

- Synchronised introduction and QA/QC of 124I-PET in the Netherlands

- Translational correlation of 124I-PET and FDG-PET with histopathology (where

available) and treatment outcome, in an explorative setting.

- To investigate whether 124I-PET has the same diagnostic, dosimetric and

prognostic yield during stimulation with rhTSH and hormone withdrawal combined

with low-idodine diet.

Study description

Background summary

The follow-up of differentiated thyroid carcinoma (DTC) primarily consists of thyroglobulin (Tg) measurements in serum during stimulation with recombinant human TSH (rhTSH). However, when recurrence is suspected, this strategy does not provide tumor localization or restaging. In case of elevated Tg the standard approach is blind treatment with a high dose radioactive 131Iodine, after which the disease may be localised in many cases using posttreatment scintigraphy. This strategy is not effective for all patients: a negative posttreatment scan and insufficient response to treatment is seen in about 40%

of cases. In these patients the treatment was futile, but did induce radiation exposure, costs, and potentially side-effects.
Recent investigations with 124Iodine PET has shown a high sensitivity for iodine-avid DTC and a high predictive value for ineffective 131I treatment. A negative 124I PET could prevent futile treatment, while a positive scan can be used to restage and optimize treatment. On the other hand, investigations with FDG PET have shown a high sensitivity for iodine-negative DTC. A negative FDG PET predicts a good prognosis, while a positive scan predicts poor prognosis and response to 131I treatment and at the same time restages for alternative treatments (resection, RT, systemic). Therefore, it is likely that combined 124I PET and FDG PET prior to blind 131I treatment will be able to influence treatment decisions.

Study objective

The study aims to determine the value of combined 124I PET and FDG PET to avoid futile treatment with 131I. Secundary aims are to validate functional imaging with histopathological correlation, and to optimize and standardize the new 124I technique during its introduction in the Netherlands.

Study design

Included patients will receive an additional combination of Iodine-124 PET/CT and FDG PET/CT prior to blind treatment with radioactive iodine. Determined tumor characteristics will be correlated with treatment outcome, to define selection criteria that will predict the treatment outcome. In selected centers, patients will also receive additional scans during treatment to evaluate optimiziation of the treatment, and / or additional scans after 6 months to determine the lesion-based response correlated with tumor characteristics.

Study burden and risks

Additional scans with a limited radiation exposure prior to treatment, and in selected cases also during and / or after treatment. There are no known or expected side effects.

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

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 invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-12-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	26-06-2012
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO Date:	12-10-2012
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27626
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37266.031.11
OMON	NL-OMON27626