Sentinel lymph node detection in thyroid carcinoma using 68Ga-tilmanocept PET/CT: A proof of concept study

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The aim of this proof-of-concept study is to investigate the feasibility of SLNB in thyroid carcinoma and optimize 68Ga-tilmanocept PET/CT the imaging protocol.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON55234

Source
ToetsingOnline

Brief title
68Ga-tilmanocept sentinel lymph node PET/CT imaging in thyroid cancer

Condition

- Endocrine neoplasms malignant and unspecified

Synonym
Thyroid cancer, thyroid carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gallium-68-Tilmanocept PET/CT, Sentinel node procedure, Thyroid carcinoma

Outcome measures

Primary outcome

* Number of SLNs determined on PET/CT

* Number of resected SLNs

Secondary outcome

* Localization of SLNs

* Pathology result of SLN compared to pathology result of rest of lymph node level

* Optimal scan protocol

* Surgical time

* Questionnaire directed to the surgeon about complexity, feasibility and additional value of various identification methods for SLNs

Study description

Background summary

Sentinel lymph node biopsy (SLNB) is a diagnostic staging procedure that is routinely applied in a variety of tumor types, but is not used in daily clinical practice for thyroid carcinoma. The procedure aims to identify the first draining lymph node(s) (SLN(s)), which is most likely to contain metastases if present. The histopathological status of the SLN should reflect the histopathological status of the rest of the lymph node level and proven metastases justify further lymph node dissection/additional treatment. Detecting SLNs close to tumor sites is hampered, since the injection site of the radiotracer, around the primary tumor, produces a large hotspot on lymphoscintigraphy possibly hiding SLNs in close proximity of the primary tumor (*shine through* effect). 68Ga-tilmanocept PET/CT is a new imaging modality with high resolution, which may limit the *shine through* effect and may

provide improved localization of SLNs nearby the injection site.

Study objective

The aim of this proof-of-concept study is to investigate the feasibility of SLNB in thyroid carcinoma and optimize 68Ga-tilmanocept PET/CT the imaging protocol.

Study design

Proof-of-concept study including 10 patients.

Study burden and risks

Patients will undergo additional ultrasound guided, peritumoral injections and two PET/CT-scans of the neck with a duration of 5 minutes. Information obtained from 68Ga-tilmanocept PET/CT may be helpful in harvesting SLNs. The extra administration of 10 MBq 68Ga-tilmanocept and 120 MBq ICG-99mTc-nanocolloid, is considered an acceptable radiation burden to the patient. Adverse reactions after injection of radiolabeled tilmanocept rarely occur. Additionally, the lymph node level(s) containing the SLN will be dissected. In part of the patients this dissection was already indicated.

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

All of the following criteria:
* The patient has provided written informed consent authorization before participating in the study
* Cytologic diagnosis of differentiated thyroid carcinoma (Bethesda 6) and will undergo a hemi- or total thyroidectomy, or cytologic diagnosis of medullary thyroid carcinoma(Bethesda 6)
* The patient is *18 years of age at time of consent
* The patient has an ECOG status of Grade 0 * 2

Exclusion criteria

Any of the following criteria:
* The patient is incapacitated
* The patient is pregnant or lactating
* The patient has a history of neck dissection, gross injury or radiotherapy to the neck that would preclude reasonable surgical dissection for this trial
* The patient will undergo minimally invasive thyroid surgery (via the axilla or trans-oral approach)
* The patient is actively receiving systemic cytotoxic chemotherapy.
* The patient is on immunosuppressive, anti-monocyte, or immunomodulatory therapy
* The patient has a preoperatively histologically proven multifocal tumor

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-12-2021
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Galliapharm/lymphoseek
Generic name:	68Ga-tilmanocept
Product type:	Medicine
Brand name:	Verdye/nanocoll
Generic name:	ICG-99mTc-nanocolloid

Ethics review

Approved WMO Date:	13-10-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	29-11-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	19-05-2022
Application type:	Amendment
Review commission:	METC NedMec

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
EudraCT	EUCTR2021-002470-42-NL
CCMO	NL72010.041.21