In-vivo multispectral optoacoustic imaging of thyroid nodules

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We aim to determine if in vivo MSOT can distinguish benign from malignant thyroid nodules by correlating and validating optoacoustic signals in vivo with pathology results.

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

Summary

ID

NL-OMON49819

Source
ToetsingOnline

Brief title
THYNODE

Condition

- Endocrine neoplasms malignant and unspecified

Synonym
thyroid nodules, thyroid tumor

Research involving
Human

Sponsors and support

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

Intervention

Keyword: MSOT, Multispectral, Optoacoustic, Thyroid nodules

Outcome measures

Primary outcome

The main study endpoint is quantification of the optoacoustic signal (HbO2, HbR, HbT, sO2, fat, water and collagen) observed by multispectral optoacoustic imaging using the MSOT Acuity Echo in vivo in patients with thyroid nodules, also in relation to the definitive pathology results (benign vs malignant).

Secondary outcome

- To explore a potential correlation between endogenous optoacoustic signals in vivo with cytology (the standard-of-care of Bethesda scoring system derived from FNA)

- To explore a potential correlation between endogenous optoacoustic signals in vivo with TIRADS ultrasonography scoring system (the scoring system used by radiologists when evaluating the thyroid nodules with ultrasonography).

Study description

Background summary

Thyroid nodules are common in clinical practice. Head and neck ultrasound is recommended as a routine examination for all patients with thyroid lesions. The Thyroid Imaging Reporting And Documentation System (TIRADS) criteria helps to estimate the risk of malignancy based on ultrasound patterns and nodule sizes guiding the performance of fine-needle-aspiration (FNA). Approximately 20% of FNA results cannot be specified whether being benign or ma-lignant tissue. A definitive diagnosis can only be made from histopathology after diagnostic (hemi)thyroidectomy. However, (hemi)thyroidectomy has disadvantages as it leads to over-treatment and has a risk of postoperative morbidity (e.g. hypothyroidism and laryngeal nerve injury). Furthermore, (hemi)thyroidectomy is known to be associated with poor quality of life. Clearly, there is an unmet need for additional diagnostic tools in order to identify malignant thyroid nodules and thereby support the decision making for treatment of the thyroid. Multispectral optoacoustic tomography (MSOT) is a novel non-invasive imaging

method that enables visualization of endogenous chromophores and exogenous contrast agents using the generation of ultrasound waves due to light absorption. Recently, this system has been used for non-invasive determination of thyroid nodules. Results show that multispectral optoacoustic imaging of thyroid nodules may distinguish benign from malignant nodules. However, a larger cohort is necessary to confirm this finding.

Study objective

We aim to determine if in vivo MSOT can distinguish benign from malignant thyroid nodules by correlating and validating optoacoustic signals in vivo with pathology results.

Study design

The current study is a non-randomized, non-blinded, single center, prospective, cross-sectional, proof of concept study.

Intervention

Included patients will undergo MSOT imaging of the thyroid nodules.

Study burden and risks

A potential risk of MSOT is cornea damage when looking straight into the laser. As everyone present in the MSOT room during imaging is obligated to wear laser safety goggles, this risk is covered. In addition, there is an interlock system in the room so that no one else can enter the room when the imaging system is activated.
The risk associated with the use of MSOT seems minor and although patients will not directly benefit from this study, results of this study will provide valuable information for our understanding of the diagnostic value of MSOT in distinguising benign from malignant thyroid nodules.

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 thyroid nodules who underwent or will undergo an ultrasonography (with TIRADS score) with FNA if indicated and will be scheduled for a (hemi)thyroidectomy if indicated;
2. Age >= 18 years;
3. Written informed consent.

Exclusion criteria

1. Medical or psychiatric conditions that compromise the patients' ability to give informed consent;
2. Previous surgery in head and neck area on the ipsilateral side of the index nodule
3. Previous radiotherapy in head and neck area
4. Pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-09-2020
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Multispectral optoacoustic tomography
Registration:	No

Ethics review

Approved WMO Date:	27-11-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-11-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL69993.042.19