The Butterfly-study: The Detection of Thyroid Cancer via VOCs using GC-IMS

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The main objective of the research is to differentiate between benign and malignant thyroid nodules using the GC-IMS for the analysis of breath, urine and blood in a (multicenter) study and reduce the amount of unnecessary surgery.

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

Summary

ID

NL-OMON51970

Source
ToetsingOnline

Brief title
The Butterfly-study

Condition

- Thyroid gland disorders

Synonym
Thyroid Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: KWF kankerbestrijding

Intervention

Keyword: Diagnostic Accuracy, Gas Chromatograph and Ion Mobility Spectrometer, Thyroid Cancer, Volatile Organic Compounds (VOCs)

Outcome measures

Primary outcome

The primary parameters of diagnostic accuracy will be sensitivity, positivity, and ROC-AUC (Area Under the Curve of the Receiver Operating Characteristics curve) of the GC-IMS model for detecting thyroid malignancy.

Secondary outcome

Secondary outcomes: A database will be maintained with patient characteristics, quality of life and emotional burden questionnaires, and surgical complications (hypoparathyroidism, bleeding, wound infection, damage to the vocal cord nerve, duration of the hospital stay) with accompanying clavien-dindo classification.

The number of unnecessary surgeries will be evaluated.

Refusing to participate in the study will be tracked to evaluate patient acceptance of the Aeonose in clinical practice. Participating patients will assess the convenience of using the Aeonose by means of a VAS scale.

Sensitivity and specificity of molecular diagnostics (BRAF mutation) on the cytology of thyroid punctures, urine and blood after regular blood sampling will be evaluated. Tissue obtained from the patients will be examined.

Study description

Background summary

Patients with a suspected thyroid nodule face an invasive and patient

unfriendly diagnostic work-up to obtain better insight in the chances of malignancy of their nodule. Therefore, patients undergo ultrasound of the thyroid gland followed by fine-needle aspiration for cytology (FNAC). The latter, resulting in the Bethesda classification, is considered as the golden standard procedure for diagnosis. In case of Bethesda III cytology, 82-94% of the surgeries are superfluous because the thyroid nodules appear to be benign after resection. This happens in Bethesda IV in 60-90% and Bethesda V in 40-55% of all thyroid surgeries. Unnecessary surgery exposes patients to unnecessary risks related to surgery. Most common thyroid surgery complications are damage to the recurrent laryngeal nerve and/or parathyroid gland. This study is of relevance because it aims at reducing unnecessary diagnostic procedures, such as a diagnostic hemithyroidectomy, and thereby reducing the risk of unnecessary harm to patients with a suspected thyroid nodule.

Study objective

The main objective of the research is to differentiate between benign and malignant thyroid nodules using the GC-IMS for the analysis of breath, urine and blood in a (multicenter) study and reduce the amount of unnecessary surgery.

Study design

Prospective (multicenter) observational study.

Study burden and risks

This study has no specific benefits for the participating patients. Possible side effects during measurements,with the sampling bags, are dizziness and nausea, usually due to hyperventilation. Other side effects are hypo- or hyper salivation during measurements. Blood will be collected during regular pre-operative blood collection, resulting in no extra skin puncture. Furthermore two quick to answer questionnaires as well as a short case report form (CRF) will be filled in by the participating patients. Using the Aeonose as a non-invasive, rapid and inexpensive diagnostic tool could be a major benefit for patients with thyroid nodules due to the faster and less invasive diagnostic process. Benefits for patients with benign thyroid diseases include the possibility to resign from unnecessary invasive treatments such as (diagnostic) surgery.

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

- Thyroid nodule requiring additional diagnostic follow-up (TI-RADS/Bethesda)
- Patients with thyroid problems requiring surgery (e.g. goiter)
- Breath collection before undergoing cytological puncture or at least 3 days after cytological puncture pre-operatively.
- > 18 year.
- Signed informed consent,

Exclusion criteria

- Other underlying malignancy, (less than 5 years ago), basal cell carcinoma not included
- Unable to participate due to comorbidities (e.g. COPD)
- Not understanding the information

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2021
Enrollment:	1500
Type:	Actual

Medical products/devices used

Generic name:	BreathSpec & FlavourSpec
Registration:	No

Ethics review

Approved WMO Date:	26-04-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	28-07-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	08-11-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-09-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	https://www.kanker.nl/trials/1085
CCMO	NL76036.068.21