Patients’ preferences for treatment for indeterminate (Bethesda 3) thyroid nodules: A discrete choice experiment

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24140

Source
Nationaal Trial Register

Brief title
DCE Thyroid nodule

Health condition

Thyroid nodule

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Patient preferences and tradeoffs in the management of indeterminate (Bethesda III) thyroid nodules

Secondary outcome

Physician preferences and tradeoffs in the management of indeterminate (Bethesda III) thyroid nodules
Differences and similarities between patients and physicians preferences

Study description

Background summary

Rationale: Thyroid nodules are very common in the general population. In nodules with suspicious ultrasound characteristics cytology is obtained via fine needle aspiration (FNA). Nodule management is then predominantly guided by the Bethesda score with each score representing a certain likelihood of malignancy. For nodules with a Bethesda score V (suspicious for malignancy) and Bethesda score VI (diagnostic for malignancy) a thyroidectomy is recommended. Also for nodules with a Bethesda score of IV (corresponding to a malignancy risk of 15-30%) a diagnostic hemithyreoidectomy is advised. How to manage nodules with a Bethesda score of III (corresponding to a malignancy risk of 5-15%) is less clear. In these nodules, FNA is often repeated. When reclassification can not be obtained, management of these nodules could consist of a diagnostic hemithyroidectomy or periodic surveillance. Each of these strategies differ in for example complication rates and diagnostic certainty. Treatment guidelines advise a personalized approach involving patient preferences. In order to implement this recommendation in clinical decision making, more understanding of patient preferences is needed. A discrete choice experiment (DCE) is an increasingly used method that has the ability to quantify the importance of distinct treatment characteristics. Knowledge about patient preferences can be very helpful in the process of shared decision making.
Objective: The aim of this study is to gain insight in the preferences of patients and physicians regarding the management of indeterminate (Bethesda 3) thyroid nodules
Study design: A multicenter discrete choice experiment (DCE) will be performed in collaboration with the Erasmus Choice Modelling Centre (ECMC). Patients will receive a single questionnaire comprised of virtual choices between theoretical treatment options that differ in treatment characteristics, otherwise known as attributes.
Study population: Patients 18 years or older and diagnosed with a thyroid nodule are eligible for inclusion. Patients will be recruited in ten hospitals in the Rotterdam area that are collaborating in the Thyroid Network. In addition, healthy individuals and patients without a thyroid disease will also be recruited.
Intervention (if applicable): An online questionnaire.
Primary study parameters/endpoints:
I. Patient preferences and tradeoffs in the management of indeterminate (Bethesda III) thyroid nodules
II. Physician preferences and tradeoffs in the management of indeterminate (Bethesda III) thyroid nodules
III. Differences and similarities between patients and physicians preferences

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be asked to fill in an online questionnaire. For patients there will be no benefit in participating. Treatment will not differ from standard care.

Study objective

Not applicable

Study design

Not applicable

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

1. Either diagnosed with a thyroid nodule (previous to analysis with FNA) or without a thyroid disease (e.g. healthy individuals or patients with other diseases)
2. Aged 18 years or older at the time of inclusion

Exclusion criteria

1. FNA of the thyroid nodule has been performed and discussed with the patient
2. Diagnosed with a thyroid disease other than a thyroid nodule (e.g. thyroid function disorder)
3. Non Dutch speaking
4. Not able to give informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2019
Enrollment:	350
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	19-05-2020
Application type:	First submission

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
NTR-new	NL8643
Other	METC Erasmus MC : MEC-2018-1666

Study results