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

Gepubliceerd: 19-05-2020 Laatst bijgewerkt: 18-08-2022

Not applicable

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24140

Bron
Nationaal Trial Register

Verkorte titel
DCE Thyroid nodule

Aandoening

Thyroid nodule

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Not applicable

Onderzoeksopzet

Not applicable

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Erasmus MC
Caroline van Kinschot

0651173097

Wetenschappelijk

Erasmus MC
Caroline van Kinschot

0651173097

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2019
Aantal proefpersonen:	350
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	19-05-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8643
Ander register	METC Erasmus MC : MEC-2018-1666

Resultaten