Dutch De-escalation pilot Study

Gepubliceerd: 27-04-2020 Laatst bijgewerkt: 07-12-2022

A hemithyroidectomy followed by active surveillance with ultrasonography results in the same oncological outcomes and survival as a total thyroidectomy and post-operative radioactive iodine (RAI) in patients with unifocal PTC 1-4 cm

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22164

Bron
Nationaal Trial Register

Verkorte titel
DDPS

Aandoening

Papillary Thyroid Cancer 1-4 cm

Ondersteuning

Primaire sponsor: No sponsors
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint consists of the participation of patients eligible for the study.

Toelichting onderzoek

Achtergrond van het onderzoek

The worldwide incidence of papillary thyroid cancer (PTC) is increasing and thyroid cancer is the most common endocrine malignancy worldwide. The incidence rises due to increased use of imaging modalities such as ultrasonography, MRI and PET/CT scan, which mainly leads to the identification of thyroid incidentalomas, small well-differentiated papillary thyroid carcinomas. Despite a shift towards a less aggressive treatment in the USA, described in the latest American Thyroid Association guideline, the Dutch guidelines are more aggressive in treating PTC. They recommend a total thyroidectomy (TTx) followed by radioactive iodine (RAI) in all patients with a PTC >1 cm. This treatment strategy comes with significant costs and morbidity rates caused by hypothyroidism, iatrogenic hypo-parathyroidism, recurrent laryngeal nerve damage, dysgeusia and xerostomia, resulting in a poor quality of life. The stable overall survival rate suggests widespread overtreatment following current treatment strategy. Therefore, changing treatment strategies for low-risk PTC patients is of great importance. This is reflected by the 2015 ATA guidelines stating that hemi thyroidectomy is sufficient for patients with low-risk PTC based on large national USA registration database studies. These studies show neither survival benefit nor difference in recurrence rate between TTx versus hemi thyroidectomy (HTx) in this group of patients. Unfortunately, the lack of strong evidence, such as randomized trials demonstrating equivalent oncological outcomes is currently withholding widespread worldwide de-escalation and is urgently required to update guidelines in non-American countries. Prior to performing such a large-scale randomized controlled trial, a pilot study is necessary to assess willingness to participate and adherence to the active surveillance strategy. This pilot study will function as a stepping stone to the aforementioned national RCT.

Doel van het onderzoek

A hemithyroidectomy followed by active surveillance with ultrasonography results in the same oncological outcomes and survival as a total thyroidectomy and post-operative radioactive iodine (RAI) in patients with unifocal PTC 1-4 cm

Onderzoeksopzet

The primary endpoint consists of the participation of patients eligible for the study, which will be calculated in percentages (%). This will be calculated when all the patients are included.

Secondary outcomes
1. Time needed to include 12 patients, which will be calculated in months after inclusion of the patients.
2. Reasons for patients to deny participation. Patients can describe the reason(s) for denial in free text. The treating physician asks an open-ended question and notes the reason for refusing participation. This will be sent to the study coordinator. This will be registered during inclusion and duration of the study.
3. Total number of patients and percentage of patients in the active surveillance group who

wish to be treated according to the current guidelines which is calculated in a categorical number (n) and a percentage (%) after inclusion of the 12 patients.
4. QOL questionnaires will be sent to the study participants before surgery, after 6 months and 12 months. These questionnaires will be saved in Castor EDC and will be evaluated after the end of the study.
5. Logistical hurdles which are described in free text, during the duration of the study. These will be evaluated after the end of the study.

Onderzoeksproduct en/of interventie

Study treatment; hemithyroidectomy and active surveillance. Standard treatment; total thyroidectomy with RAI.

Contactpersonen

Publiek

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06-20956464

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Able to undergo surgery
- Age of 18 years and older
- Diagnosed with unilateral papillary thyroid cancer with a diameter of 1-4 cm, as defined by:
o Histologically proven PTC after diagnostic hemithyroidectomy 1-4cm

or
o Cytologically proven Bethesda 6
or
o Cytologically proven Bethesda 5 nodule with confirmed BRAF mutation
- Size of index nodule / tumor must be between 1 and 4cm, measured by ultrasound or on histopathology. Histopathology may overrule ultrasound measurements.
- Ultrasound of the neck excluding lymph node involvement
- Signed informed consent by patient

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Extrathyroidal extension upon definitive histology or ultrasound examination
- Lymph node involvement confirmed by ultrasound and FNA prior to randomization
- Multifocality
- Aggressive histology (e.g. tall cell, columnar cell)
- A contralateral nodule requiring intervention (if applicable)
- Pregnant women
- Insufficient understanding of the Dutch language to understand the study documents
- Minors (age < 18 years) and incapacitated subjects do not meet the eligibility criteria and will therefore not be enrolled

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2020

Aantal proefpersonen:	12
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	27-04-2020
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	NL8977
Ander register	METC Erasmus MC : MEC-2020-0427

Resultaten