Onderzoek naar kwaliteit van leven bij patiënten die radiofrequente ablatie hebben ondergaan voor een goedaardige schildklier knobbel

Gepubliceerd: 12-12-2018 Laatst bijgewerkt: 13-12-2022

Current standard treatments for symptomatic benign thyroid nodules (SBTN) are surgery or radioactive iodine. However, these interventions pose a risk to an otherwise healthy person. Therefore, minimally invasive alternatives have been explored....

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

Samenvatting

ID

NL-OMON21601

Bron
NTR

Verkorte titel
SURF pilot study

Aandoening

Symptomatic benign thyroid nodule
Symptomatisch benigne schildklier nodus

Ondersteuning

Primaire sponsor: Erasmsus Medical Center, Rotterdam
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study endpoint is to assess the quality of life as measured by SF-36 and ThyPRO-39 in patients who underwent RFA as compared to patients who underwent thyroid surgery in case of a SBTN.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Current standard treatments for symptomatic benign thyroid nodules (SBTN) are surgery or radioactive iodine. However, these interventions pose a risk to an otherwise healthy person. Therefore, minimally invasive alternatives have been explored. Radio frequent ablation (RFA) is a new and successful technique used to treat symptomatic benign thyroid nodules. Because RFA is a relatively new used technique in our hospital, it is of utmost importance to assess the experience of this technique in terms of efficacy, risks and patient satisfaction before it becomes a routine treatment.

Objective: Therefore, the primary objective of this pilot study is to assess the quality of life as measured by SF-36 and ThyPRO-39 in patients who underwent RFA as compared to a historical cohort of patients who underwent thyroid surgery (hemi thyroidectomy) in case of a SBTN.

Study design: This study is an observational pilot study in which we will measure the health related quality of life in patients who underwent RFA and compare it to a historical cohort of patients who underwent thyroid surgery.

Study population: All adult patients who will undergo or already underwent RFA in the Erasmus MC in case of a SBTN will be asked to participate in this study. A total of 15 new patients will be included in this study.

Main study parameters/endpoints: Main study endpoint is to assess the quality of life as measured by SF-36 and ThyPRO-39 in patients who underwent RFA as compared to patients who underwent thyroid surgery in case of a SBTN.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden associated with participation in this trial involves filling in two questionnaires at four time points. No benefits will be gained from the participation in the trial. There are no risk involved since patients will only be asked to fill in questionnaires.

Doel van het onderzoek

Current standard treatments for symptomatic benign thyroid nodules (SBTN) are surgery or radioactive iodine. However, these interventions pose a risk to an otherwise healthy person. Therefore, minimally invasive alternatives have been explored. Radio frequent ablation (RFA) is a new and successful technique used to treat symptomatic benign thyroid nodules. Because RFA is a relatively new used technique in our hospital, it is of utmost importance to assess the experience of this technique in terms of efficacy, risks and patient satisfaction before it becomes a routine treatment. Therefore, the primary objective of this pilot study is to assess the quality of life as measured by SF-36 and ThyPRO-39 in patients who underwent RFA as compared to a historical cohort of patients who underwent thyroid surgery (hemi thyroidectomy) in case of a SBTN.

Onderzoeksopzet

The duration of patient participation will be up to 1 year. Patients will be asked to fill in two questionnaires at four time points. Pre RFA and 3, 6 and 12 months post RFA.

Onderzoeksproduct en/of interventie

none

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age≥18 years

- Patient will undergo or already underwent RFA for a SBTN

- Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age <18 years

- Prior thyroid surgery

- Patients who are not able to provide written informed consent

- No adequate understanding of the Dutch language

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	11-12-2018
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-12-2018
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	NL6388
NTR-old	NTR7660
Ander register	METC Erasmus MC : MEC-2018-1616

Resultaten