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

No registrations found.

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

Summary

ID

NL-OMON21601

Source
NTR

Brief title
SURF pilot study

Health condition

Symptomatic benign thyroid nodule
Symptomatisch benigne schildklier nodus

Sponsors and support

Primary sponsor: Erasmsus Medical Center, Rotterdam
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

not applicable

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

- Age≥18 years

- Patient will undergo or already underwent RFA for a SBTN

- Informed consent

Exclusion criteria

- Age <18 years

- Prior thyroid surgery

- Patients who are not able to provide written informed consent

- No adequate understanding of the Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-12-2018
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-12-2018
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	NL6388
NTR-old	NTR7660
Other	METC Erasmus MC : MEC-2018-1616

Study results