Behandeling met radioactief jodium versus hemithyreoïdectomie, welke behandeling heeft het beste effect heeft op klachten bij patiënten met symptomatisch euthyreoot struma

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Treatment of patients with a benign euthyroid goitre, with either radioactive Iodine or hemithyroidectomy, has a different effect on symptoms and quality of life (QoL)

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29617

Source
NTR

Brief title
OPERA!

Health condition

benign euthyroid goitre struma

Sponsors and support

Primary sponsor: - AMC
- Flevoziekenhuis
Source(s) of monetary or material Support: self-funding

Intervention

Outcome measures

Primary outcome

reduction of symptoms 12 months after treatment measured with ThyPro Questionnaire

Secondary outcome

- Quality of life measured by EQ-5D-5L questionnaire after 6 months and 1-5 years
- Voice impairment after 6 months and 1-5 years as measured by the Voice Handicap Index, a specific questionnaire for voice impairment detection a
- Effect of treatment on symptoms after 6 months, 2, 3, 4 and 5 years after treatment as measurd by the ThyPRO questionnairre
- Goitre volume as measured on a CT-scan 12 months after treatment
- Serum TSH, T4 levels, PTH (standard 2-6 weeks after treatment or if measured under routine care at any time during follow-up)
- Hypo- or hyperthyroidism
- Peri-operative complications: vocal cords palsy
- Complications of radioactive iodine

Study description

Background summary

Rationale: Euthyroid benign symptomatic goitre can be treated with radioactive 131-Iodine or resection of the thyroid (hemithyroidectomy). Resection of a large goitre combines an operative risk for bleeding/infection, vocal cord apraxia/palsy and a small risk of hypothyroidism with an almost 100% relieve of symptoms. Radioactive Iodine treatment combines a risk for hypothyroidism, hyperthyroidism or thyroiditis with an estimated 40-60% reduction in goitre size. Both treatment options are currently performed, but have never been compared in a randomised study.

Objective: To compare the effect of radioactive Iodine or hemithyroidectomy on the symptoms and quality of life (QoL) of patients with a benign euthyroid goitre.

Study design: Prospective open-label randomised trial.

Study population: Patients with treatment desire or treatment indication for symptomatic benign euthyroid goitre, including both one-sided as double-sided goitre with a total volume of at least 40 ml (for one side). Patients should be candidates for both surgical treatment and radioactive iodine treatment.

Intervention: Radioactive iodine treatment conform local treatment protocols or hemithyroidectomy with resection of the largest lobe. Main study parameters/endpoints: Primary outcome is the reduction of symptoms 12 months after treatment, as measured by a decrease of complaints on self-reported QoL questionnaire (ThyPRO). Secondary outcomes are goitre volume as measured on a CT-scan without contrast 1 year after treatment, complications (vocal cords palsy, hypo- or hyperthyroidism) and self-reported QoL after two to five years after treatment..

Sample size calculation: We use a superiority design. In literature a decrease of symptoms after surgery or RAI treatment is described around 50%-80%. Based on this literature we expect a mean difference ThyPRO of 16 points (from 36 to 20) between the two groups, in favour of hemithyroidectomy. Using a 2-sided alpha of 0.05 and a power of 80 percent 29 patients per group are necessary. Expecting a drop out of 10% 70 patients will be included.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients are currently treated with either radioactive iodine and hemithyroidectomy, based on doctor’s or patient’s preference. Participation in this study does not increase the existing risks of treatment. 12 months after treatment a CT-scan of the neck without contrast will be made as part of this study. The radiation exposure of a CT-scan of the neck is estimated to be 3.5 mSv for the patients. The exposure is within the category IIb (1-10mSv) of the International Commission on Radiological Protection (ICRP), which qualifies as: intermediate risk.

Study objective

Treatment of patients with a benign euthyroid goitre, with either radioactive Iodine or hemithyroidectomy, has a different effect on symptoms and quality of life (QoL)

Study design

- baseline
- routine post-treatment
- 6 months
- 1, 2, 3, 4, 5 mars

Intervention

Radioactive iodine treatment
Hemithyroidectomy

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Eligibility criteria

Inclusion criteria

- Patients with symptomatic goitre
- Goitre size larger than 40 ml on one side determined on CT
- Patients accept both treatment modalities
- TSH between 0,5-5,0 mE/L (euthyroidism) without Thyroid suppletion
- Not pregnant or childwish within 6 months after treatment
- Able to undergo surgery as well as radioiodine treatment
- 18 years or older

Exclusion criteria

- Goitre suspicious of malignancy on imaging
- Bethesda 5 or 6 cytology
- Hyperthyroidism
- Previous history of thyroid surgery or radioactive iodine
- Not eligible for general anesthesia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-06-2018
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-05-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46798
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7041
NTR-old	NTR7246
CCMO	NL64148.018.18
OMON	NL-OMON46798

Study results