Radioactive iodine treatment versus hemithyroidectomy in patients with symptomatic benign euthyroid goitre

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

Ethical review	Approved WMO
Status	Will not start
Health condition type	Thyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON46798

Source
ToetsingOnline

Brief title
Opera!

Condition

- Thyroid gland disorders
- Endocrine gland therapeutic procedures

Synonym
Struma, zwelling schildklier

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: euthyroid, goiter, hemithyroidectomy, radioactive iodine

Outcome measures

Primary outcome

Primary outcome is the reduction of symptoms 12 months after treatment, as measured by a decrease of complaints on self-reported QoL questionnaire (THYRPRO).

Secondary outcome

Secondary outcomes are goiter volume as measured on a CT-scan without contrast 1 year after treatment and complications (vocal cords palsy, hypo- or hyperthyroidism.

Study description

Background summary

Euthyroid benign symptomatic goiter can be treated with radioactive 131-Iodine or resection of the thyroid. Resection of a large goiter combines an operative risk for bleeding/infection and vocal cord apraxia/palsy 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 goiter size. Both treatment options are currently performed, but have never been compared in a randomised study.

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 goiter.

Study design

Prospective open-label randomised trial

Intervention

Radioactive iodine treatment conform local treatment protocols or hemithyroidectomy with resection of the largest lobe.

Study burden and risks

Patients are currently treated with both radioactive iodine and hemithyroidectomy, based on doctor*s or patient*s preference. Participation in this study does not increase the existing risks. The average dose of a CT scan of the neck is estimated to be 6 mSv for the patients. The exposure is within the category IIb (1-10mSv) of the Netherlands Commission on Radiation Dosimetry and Subcommittee Radation Doses & Risk Estimation for Medical Diagnostics and Research, which qualifies as a low level of risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

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 64 months after treatment
- Able to undergo surgery as well as radioiodine treatment (hoe te definieren)
- Able to fill in questionnaires and give Informed Consent
- 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 phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	70

Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	theracap 131
Generic name:	radioactive iodine

Ethics review

Approved WMO Date:	26-02-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-09-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29617

Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2017-005135-16-NL
CCMO	NL64148.018.18

Study results

Summary results
Trial never started