Ultrasound-guided Radiofrequency Ablation versus radioactive iodine as Treatment for Hyperthyroidism caused by Solitary Autonomous Thyroid Nodules

Published: 31-08-2021
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This study has been transitioned to CTIS with ID 2024-515602-34-01 check the CTIS register for the current data. To assess which treatment leads to the best patient outcome on the short term (1 year) and the long term (5 years)

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Thyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON54080

Source
ToetsingOnline

Brief title
RABITO study

Condition

- Thyroid gland disorders

Synonym
hyperactive nodule, thyroid lump

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: ZonMw,MML medical

Intervention

Keyword: hyperthyroidism, radioactive iodine, radiofrequency ablation, toxic thyroid nodule

Outcome measures

Primary outcome

Incidence of irreversible hypothyroidism

Secondary outcome

- one year cure rate

- course of thyroid function

- nodule volume

- treatment related thyroiditis

- adverse effects

- standardized iodine versus local iodine

- cost effectiveness

- (thyroid related) quality of life

- factors for implemantation

Study description

Background summary

In about 5-10% of patients presenting with hyperthyroidism the elevated thyroid hormone levels are produced by a hyperactive
thyroid node (HTN) . The current standard of care for hyperthyroidism caused by a solitary HTN is treatment with radioactive iodine
(RAI). It is very effective in controlling hyperthyroidism but is associated with a high risk of irreversible hypothyroidism, increasing
from 10 - 35% at one year to up to 60% after 20 years. These patients will need treatment with thyroid hormone for life. This

implies that the long-term cure rate of RAI, defined as the percentage of patients with a persistent normalization of thyroid function, is low. Recently, radiofrequency ablation (RFA) has been introduced as a new treatment option. RFA leads to a normalization of thyroid function in 60 - 75% of patients within one year, and is associated with a 3% risk of permanent hypothyroidism. It is currently not known which treatment is most effective in establishing the highest long-term cure rates. We hypothesize that RFA treatment is associated with a lower rate of irreversible hypothyroidism, and therefore a higher long-term cure rate.

Study objective

This study has been transitioned to CTIS with ID 2024-515602-34-01 check the CTIS register for the current data.

To assess which treatment leads to the best patient outcome on the short term (1 year) and the long term (5 years)

Study design

Multicentre, randomized controlled trial, nested within a prospective cohort study with a 5-year follow-up

Intervention

Patients agreeing to participate in randomization will be randomized to receive treatment with either RAI (group 1), or RFA (group 2). Patients declining randomization but agreeing to follow-up will receive the local standard treatment with either RAI, Surgery or anti-thyroid drugs (group 3).

Study burden and risks

Patients randomized for this study receive a treatment and follow-up scheme closely resembling clinical practice. In addition, patients will be asked to fill out questionnaires on (thyroid related) quality of life, medical consumption and patient experience, at baseline and 3 times in the first year after treatment. Patients randomized to the RFA arm will undergo RFA according to current practice guidelines as performed for non-functioning thyroid nodules which is associated with a low procedure related risk profile. Procedure related minor events occur in 5% of patients and include local haemorrhage and swelling. Transient worsening of hyperthyroidism due to post RFA thyroiditis occurs in less than 5% of patients. A severe adverse event, transient laryngeal nerve damage, has been observed in 0.5% of patients and irreversible

hypothyroidism is expected to occur in less then 3% of patients.

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

- Age > 18 years
- Hyperthyroidism or subclinical hyperthyroidims caused by a solitary hyperactive thyroid nodule (HTN), either located in an otherwise normal thyroid gland, or in a multinodular goitre (MNG)
- Treatment with RAI indicated and eligible for RFA
- Signed informed consent

Exclusion criteria

- Multifocal HTN
- HTN > 50 mm
- Presence of a medical device susceptible to disturbances caused by RFA generated currents
- Patients with physical or behavioural disorders that preclude safe isolation in radiation protection rooms, or safe RFA procedure under local anesthesia
- Uncorrectable hemorrhagic diathesis
- Pregnancy

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-11-2021
Enrollment:	232
Type:	Actual

Medical products/devices used

Generic name:	Viva radiofrequency generator or AMICA GEN AGN-H-1.2 generator and an 18 gauge internally cooled ele
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Sodium Iodide (I-131) Capsules T, capsules 37-7400 MBq/st

Generic name:	Sodium Iodide (I-131)

Ethics review

Approved WMO Date:	31-08-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-09-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-03-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-05-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-11-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-04-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-07-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EU-CTR	CTIS2024-515602-34-01
EudraCT	EUCTR2021-001941-11-NL
CCMO	NL77101.091.21