Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative study of Ethanol injection, Radiofrequency Ablation, and Levothyroxine Therapy in Patients with Benign Thyroid Nodules: A Multicenter Randomized clinical Trial in Iran

Protocol summary

Study aim

Comparison of the effects of ethanol injection, radiofrequency ablation, levothyroxine therapy in the treatment of benign thyroid nodules based on nodule size changes in ultrasonography.

Design

Randomizes clinical trial with control group, parallel, single-blinded, on 91 patients through Block Randomization with blocks of 6.

Settings and conduct

In this multicenter study, after identifying the patient group, 31 patients underwent one-session radiofrequency ablation therapy, 30 patients underwent one session of 96% ethanol injection, and 30 patients underwent 6-month treatment with levothyroxine (standard dose 1.6-2.1 µg/kg/Per day), eventually this study will be single-blinded (data analyzer)

Participants/Inclusion and exclusion criteria

Inclusion criteria Normal thyroid test TSH, T4, T3, T3RU, Anti TPO History of pressure sign/nodule growth. Benign biopsy specimen. Normal blood calcitonin levels The patient has not received previous treatment for thyroid nodules Exclusion criteria: Nodules with malignant features Malignant or non-diagnostic pathology after biopsy under ultrasound guidance Pregnancy Abnormal thyroid function test or abnormal calcitonin

Intervention groups

Intervention medical treatment in form of suppression therapy with levothyroxine and intervention procedure with ethanol injection and radiofrequency ablation (RFA); levothyroxine treatment group is considered as control group and there is no placebo.

Main outcome variables

complications and efficacy of treatment with ethanol injection, radiofrequency ablation and levothyroxine therapy based on nodule size changes in ultrasound, gender, family history of thyroid cancer and changes in laboratory variables in the first, third and sixth months after treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140712018457N6**
Registration date: **2022-07-09, 1401/04/18**
Registration timing: **retrospective**

Last update: **2022-07-09, 1401/04/18**
Update count: **0**

Registration date

2022-07-09, 1401/04/18

Registrant information

Name

Hossein Ghanaati

Name of organization / entity

Advanced Diagnostic and Interventional Radiology Research Center (ADIR), Tehran University of Medica

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2022-05-05, 1401/02/15

Actual recruitment start date

2021-10-07, 1400/07/15

Actual recruitment end date

2022-05-21, 1401/02/31

Trial completion date

empty

Scientific title

Comparative study of Ethanol injection, Radiofrequency Ablation, and Levothyroxine Therapy in Patients with Benign Thyroid Nodules: A Multicenter Randomized clinical Trial in Iran

Public title

Comparative study of the different treatment methods in size reduction of the benign thyroid nodules

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Normal thyroid test including TSH, T۴, T۳, T۳RU, Anti TPO The nodule has grown or the patient reports pressure sign FNA biopsy specimen or core needle biopsy under ultrasound guidance is benign. Normal blood calcitonin level The patient has not received previous treatment for thyroid nodules

Exclusion criteria:

Malignant sonographic features of thyroid nodules Malignant or non-diagnostic lesions in pathology results Pregnancy Abnormal thyroid function tests or abnormal calcitonin

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **90**

Actual sample size reached: **91**

Randomization (investigator's opinion)

Randomized

Randomization description

After getting familiar with the study design and obtaining the informed consent form, patients enter the intervention group (ethanol or radiofrequency therapy) or medical treatment (levothyroxine) group using block randomization method with block of 6.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, each group is given a specific name (such as A, B, and C) so that the nature of the group's treatment is unknown to the person who follows up and evaluates the results within 6 months (indeed the evaluator is blinded).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Imam Khomeini Hospital Medical Ethics Committee

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2021-10-06, 1400/07/14

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.248

Health conditions studied

1

Description of health condition studied

Benign thyroid nodule

ICD-10 code

E04.1

ICD-10 code description

Nontoxic single thyroid nodule

Primary outcomes

1

Description

Size of thyroid nodule

Timepoint

one, three and six month following related treatment.

Method of measurement

Measurement of thyroid nodules size using ultrasound based on millimeters

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients treated with radiofrequency ablation and ethanol injection

Category

Treatment - Other

2

Description
Control group: patients treated with Levothyroxine
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital complex
Full name of responsible person
Hossein Ghanaati
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Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
1
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Professor of radiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available