Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Effectiveness of radiofrequency ablation therapy with ultrasound guidance in thyroid nodules

Protocol summary

Study aim
Determining the effectiveness of ultrasound-guided radiofrequency ablation therapy in the treatment of thyroid nodules

Design
The current study is a non-randomized clinical trial. It should be noted that there is no randomization, blinding, or control group in this study.

Settings and conduct
In this study, patients in the intervention group who visited the office of Dr. Talaei Zadeh and Dr. Motamedfar during the research registration period were entered in the study based on inclusion criteria and exclusion criteria. Patients are then referred to the office of Dr. Motamed Far, an interventional radiologist, for an ultrasound-guided RFA procedure, and this procedure is performed on them; then, 3 months after the first RFA session for their fallopian tubes, they undergo a thyroid ultrasound.

Participants/Inclusion and exclusion criteria
Patients must be over 18 years of age. The diagnosis of autonomous nodule or benign thyroid nodule must be definitive and documented. Patients with residual thyroid after thyroid cancer surgery. Patients with metastatic lymph nodes after LND surgery for thyroid cancer. Patients with benign thyroid nodules less than 20 mm without clinical symptoms. Patients with a benign thyroid nodule greater than 20 mm with clinical symptoms. Patients with autonomous thyroid nodules less than 20 ml.

Intervention groups
In current study, the intervention will be performed on patients with benign nodules, autonomous thyroid nodules, thyroid remnants remaining after thyroid cancer surgery, and metastatic lymph nodes remaining after thyroid cancer lymph node dissection surgery based on inclusion and exclusion criteria.

Main outcome variables
The thyroid nodule volume reduction rate (VRR) is the result of dividing the difference between the pre-procedure and post-procedure volume of the thyroid nodule by the pre-procedure volume multiplied by 100.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251024067738N1**
Registration date: **2025-11-04, 1404/08/13**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-04, 1404/08/13**
Update count: **0**

Registration date
2025-11-04, 1404/08/13

Registrant information

Name
Nima Farhadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-03, 1404/08/12

Expected recruitment end date
2026-02-01, 1404/11/12

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of radiofrequency ablation therapy with ultrasound guidance in thyroid nodules

Public title

Radiofrequency ablation in thyroid nodules

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a definitive and documented diagnosis of autonomous nodule or benign thyroid nodule. Patients must be over 18 years of age. Patients with residual thyroid after thyroid cancer surgery. Patients with metastatic lymph nodes after lymph node dissection surgery for thyroid cancer. Patients with benign thyroid nodules less than 20 mm without clinical symptoms. Patients with a benign thyroid nodule greater than 20 mm with clinical symptoms. Patients with autonomous thyroid nodules less than 20 ml.

Exclusion criteria:

Patients who do not consent to participate in the research. Patients with known cases of dementia or psychiatric cognitive disorders. Patients under 18 years of age. Patients in whom the diagnosis of autonomous nodule or benign thyroid nodule is not definitive and documented. Patients with autonomous nodules with a volume greater than 20 ml.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics commitee, Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz, Golestan Boulevard, Ahvaz Jundishapur University of Medical Sciences, secretary for Research, Research Ethics commitee

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2025-10-22, 1404/07/30

Ethics committee reference number

IR.AJUMS.REC.1404.370

Health conditions studied

1

Description of health condition studied

Benign thyroid nodules - Autonomous thyroid nodule - Residual thyroid after thyroid cancer surgery - Residual metastatic lymph nodes after lymph node dissection for thyroid cancer.

ICD-10 code

E04.1

ICD-10 code description

Nontoxic single thyroid nodule

Primary outcomes

1

Description

Thyroid nodule volume reduction rate: It is created by dividing the difference between the pre- and post-thyroid nodule volume by the pre-thyroid nodule volume multiplied by 100.

Timepoint

The volume of the thyroid nodule or lymph node is examined first and 3 and 6 months after the procedure.

Method of measurement

The size of the thyroid nodule or lymph node is determined by ultrasonography of the thyroid or neck.

Secondary outcomes

1

Description

Minor and major complications resulting from ultrasound-guided radio frequency ablation procedure

Timepoint

Beginning of study, 3 and 6 months after the procedure

Method of measurement

History, physical examination, thyroid and neck

ultrasound, and thyroid function test

Intervention groups

1

Description
Intervention group: Patients with benign nodules, autonomous thyroid nodules, thyroid remnants remaining after thyroid cancer surgery, and metastatic lymph nodes remaining after thyroid cancer lymph node dissection surgery
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Ahvaz
Full name of responsible person
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Sponsors / Funding sources

1

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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
Ahvaz University of Medical Sciences
Proportion provided by this source
100
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
Ahvaz University of Medical Sciences
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Professor of Cancer Surgery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the human nature of the current study and information about the demographics, course of treatment, and clinical findings of the patients participating in this study, based on the principles of medical confidentiality and the principles of ethics in research, there is no desire to publish the data file after the end of the clinical trial.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Due to the human nature of the current study and information about the demographics, course of treatment, and clinical findings of the patients participating in this study, based on the principles of medical confidentiality and the principles of ethics in research, there is no desire to publish the data file after the end of the clinical trial.

When the data will become available and for how long

Due to the human nature of the current study and information about the demographics, course of treatment, and clinical findings of the patients participating in this study, based on the principles of medical confidentiality and the principles of ethics in research, there is no desire to publish the data file after the end of the clinical trial.

To whom data/document is available

Only the reviewers of the journal to which the article resulting from this research project is submitted will be allowed to use the data from this clinical trial after going through the process of obtaining permission from the Research Ethics Committee and the Vice President for Research of Ahvaz University of Medical Sciences.

Under which criteria data/document could be used

The use of data from this research for purposes other than publishing the article with the coordination of the corresponding author is not permitted.

From where data/document is obtainable

To obtain data, you can contact the corresponding author for the current research.

What processes are involved for a request to access data/document

Sending an email to the corresponding author

Comments