

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Clinical trial of Electrical Impedance Spectroscopy of Thyroid nodules for real-time discrimination of benign, atypical, and malignant lesions in patients candidate for surgery or biopsy

Protocol summary

Study aim

Differentiation of benign and malignant thyroid lesions in patients candidate for surgery and assistance in the diagnosis of lesions with non-diagnostic FNA and AUS.

Design

A pragmatic, single group, not blinded, not randomized, an intervention group, sample size 384 patients.

Settings and conduct

Considering inclusion and exclusion criteria, a double-layer sterilized G18-G22 needle is inserted into the solid mass or suspicious lymph node in the surgery room. Then a low power electrical signal of varying frequency is applied between the inner and outer needles of the probe. The electrical impedance is then measured and classification parameters are determined by analyzing phase and impedance diagrams for distinguishing benign and malignant lesions. The probe is inserted in the thyroid nodule under the sonography guidance and measurement is accomplished.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with thyroid lesions candidate for total thyroidectomy of lobectomy, patients candidate for parathyroid surgery, patients candidate for lymph node dissection, patients candidate for Thyroid or neck lymph nodes biopsy No exclusion criteria for patients candidate for Thyroid surgery High blood pressure patients or patients taking anticoagulants (for ETS tests before biopsy)

Intervention groups

Biopsy candidates: a G18 modified sterilized needle is inserted into the tissue under the sonography guidance, before the biopsy and the impedance data is recorded. Surgery candidates: before excision of the thyroid nodule and suspicious lymph nodes, the needle is inserted into the tissue.

Main outcome variables

Real-time distinguishment of benign and malignant

thyroid lesions, metastatic lymph node detection, parathyroid tissue detection, and cancer type evaluation if possible (medullary, papillary, and follicular)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190904044697N7**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **prospective**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

Registration date

2021-02-16, 1399/11/28

Registrant information

Name

Mohammad Abdolahad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 8367

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of Electrical Impedance Spectroscopy of Thyroid nodules for real-time discrimination of benign, atypical, and malignant lesions in patients candidate for surgery or biopsy

Public title

Thyroid Electrical Impedance Spectroscopy

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients candidate for Thyroid surgery Patients candidate for Parathyroid surgery Patients candidate for dissection of neck lymph nodes Patients candidate for Thyroid biopsy Patients candidate for neck lymph nodes biopsy

Exclusion criteria:

No exclusion criteria for patients candidate for Thyroid surgery High blood pressure patients (for ETS tests before biopsy) Patients taking anticoagulants (for ETS tests before biopsy)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **384**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

No.23, 16 Azar Ave, Enghelab Ave, Tehran, Iran

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Approval date

2018-08-18, 1397/05/27

Ethics committee reference number

IR.TUMS.VCR.REC.1397.355

Health conditions studied**1****Description of health condition studied**

Malignant neoplasm of Thyroid

ICD-10 code

C73

ICD-10 code description

Malignant neoplasm of Thyroid

2**Description of health condition studied**

Benign tumor with solid mass

ICD-10 code

D34

ICD-10 code description

Benign neoplasm of thyroid gland

3**Description of health condition studied**

Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck

ICD-10 code

C77.0

ICD-10 code description

Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck

Primary outcomes**1****Description**

The pathologic classification of thyroid nodules or metastatic neck lymph nodes

Timepoint

before dissection of the thyroid nodule, suspicious lymph node or parathyroid nodule for patients candidate for surgery / before FNA or CNB from thyroid nodule or suspicious lymph nodes for patients candidate for biopsy

Method of measurement

Electrical Impedance Spectroscopy (impedance phase slope in frequency ranges of 100kHz to 500 kHz)

Secondary outcomes

1

Description

investigation of ETS in decreasing unrequired biopsy or surgery of benign thyroid lesions

Timepoint

after finishing the trial

Method of measurement

By comparing FNA pathology results and impedance spectroscopy results of patients candidate for thyroid surgery

Intervention groups

1

Description

Intervention group 1: Our surgical colleagues select some patients with solid tumors that are candidates for surgery and applying ETS based on inclusion criteria. After anesthetizing the patient, opening the skin around the neck, and giving access to the thyroid, the surgeon inserts the sterilized probe into the areas that he or she thinks are the most suspicious region. Then, by applying the electrical voltage, measurements are made in those areas according to the physician's discretion, and the raw spectroscopy information and classification parameters are stored and recorded, and the probe is removed without any sampling. Then, sampling is done from the same place to send to the pathology. Preliminary results of the sample pathology are received and re-diagnosed as blind by another pathologist.

Category

Diagnosis

2

Description

Intervention group 2: Our radiological colleagues select some patients with solid tumors that are candidates of CNB or FNA for applying ETS based on inclusion and exclusion criteria. After anesthetizing the patient's skin, the radiologist inserts the sterilized probe into the areas that he or she thinks are the most suspicious regions. Then, by applying an electrical voltage, measurements are made in those areas according to the physician's discretion, and the raw spectroscopy information and classification parameters are stored and recorded, and the probe is removed without any sampling. Then, FNA or CNB is done from the same place to send to the pathology. Preliminary results of the sample pathology are received and re-diagnosed as blind by another pathologist.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital
Full name of responsible person
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2

Recruitment center

Name of recruitment center
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3

Recruitment center

Name of recruitment center
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Recruitment center

Name of recruitment center

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Web page address<https://tiradsono.com/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran Nano Fund

Full name of responsible person

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Street addressNo. 38, West Nastaran Ave (Arab), Khorramshahr St.,
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Web page address<http://nanofund.ir>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran Nano Fund

Proportion provided by this source

70

Public or private sector

Private

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**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Abdolahad

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Electrotechnical specialist in onco-surgery and cancer therapy

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Position

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Person responsible for updating data**Contact**

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Cancer Specialist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

60% of the information about the primary outcome after de-identifying the participants, can be shared.

When the data will become available and for how long

Starting six months after publication.

To whom data/document is available

The data will be available for medical staff and academic institutions

Under which criteria data/document could be used

Non-identifiable personal data will not be usable for the applicant and will only inform the patient of a positive clinical trial that the device is functioning properly.

From where data/document is obtainable

Applicants can request data access via email. The data will be available to the applicant in a categorized manner with pathology reports.

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

We will send the data to the applicant in one week.

Comments