

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of levothyroxine in comparison to placebo on thyroid nodule volume in patients with benign thyroid nodule during 2 year follow up

Protocol summary

Summary

The purpose of this study is to investigate the effect of levothyroxine on the volume of benign thyroid nodule. 80 patients, 20 to 60 years old, with palpable thyroid nodule in physical exam and being in euthyroid state, referring to endocrinology subspecialty clinic of Razi Hospital in Rasht city, are recruited in the study after making sure that the nodule is benign confirmed with FNA (Fine needle aspiration). Size of nodules are measured by sensitive ultrasound methods. Then patients are divided in two groups of intervention and control, with using strata random block. The patients of intervention group receive levothyroxine with the therapeutic dose of 1.8 µg/kg in which levothyroxine dose is coordinated with TSH (Thyroid-stimulating hormone) serum level after 6 weeks suppressive treatment in order to bring TSH serum level between 0.1 to 0.5 mU/L and is controlled every 3 months. The control group receives placebo with similar dose. Both groups are followed up for 24 months. Nodule size and TSH serum levels are measured and compared between two groups in the beginning, after 6 months, after 12 months; and after 24 months of the study. Neither the patients, nor the sonographer are aware which therapy is allocated to which patient. All patients will be enrolled in the study after giving consent.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092624021N2**

Registration date: **2016-10-31, 1395/08/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-31, 1395/08/10

Registrant information

Name

Ahmad Alizadeh

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2016-09-26, 1395/07/05

Expected recruitment end date

2016-10-11, 1395/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of levothyroxine in comparison to placebo on thyroid nodule volume in patients with benign thyroid nodule during 2 year follow up

Public title

evaluation of the effect of levothyroxine on benign thyroid nodule volume

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria:patients with single or multi thyroid nodules that have been proved to be benign with FNA
 Exclusion criteria:age under 20 and over 60; hypo or hyper thyroidism; history of using levothyroxine during past year; osteoporosis ; pregnancy; cardiovascular disease

Age
 From **20 years** old to **60 years** old

Gender
 Both

Phase
 2

Groups that have been masked
No information

Sample size
 Target sample size: **80**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features
 block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

Street address

Gaz square

City

Rasht

Postal code

419389334

Approval date

2016-09-18, 1395/06/28

Ethics committee reference number

IR.GUMS.REC.1395.185

Health conditions studied

1

Description of health condition studied

Thyroid nodule

ICD-10 code

E00-E07

ICD-10 code description

Disorders of thyroid gland

Primary outcomes

1

Description

thyroid nodule volume

Timepoint

beginning of assessment,6 months later after intervention , 12 months later ,18 months later , 24 months later

Method of measurement

ultrasound

Secondary outcomes

1

Description

TSH

Timepoint

before intervention, 6 weeks later, then every 3 months

Method of measurement

laboratory kit

Intervention groups

1

Description

intervention group:using levothyroxine with therapeutic dose of 1.8 µg/kg, daily, for 24 months

Category

Treatment - Drugs

2

Description

control group:using placebo half to one tablet, daily, for 24 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology Clinic of Razi Hospital

Full name of responsible person

Dr. sa'eed kalantari

Street address

Sardare Jangal Street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Dr. Rasool Tabari KHomeirani

Street address

Gaz square

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Guilan University of Medical Sciences, Vice chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Razi hospital

Full name of responsible person

Ahmad Alizadeh

Position

Associate Professor

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majid pour emam ali

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Radiology resident

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty