Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessment of the effect of levothyroxine in comparison to placebo on thyroid nodule volume in patients with benign thyroid nodule during 1 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.60 patients, 20 to 60 years old, with palpable thyroid nodule in physical exam and being in euthyroid state, referring to endocrinology subspeciality clinic of Razi Hospital in Rasht city, are recruited in the study after making sure that the nodule is benign confirmed with FNA.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 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 12 months.Nodule size and TSH serum levels are measured and compared between two groups in the beginning, after 6 months, and after 12 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: **IRCT2015091424021N1**
Registration date: **2015-11-21, 1394/08/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-11-21, 1394/08/30

Registrant information

Name
Ahmad Alizadeh
Name of organization / entity
Guilan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences vice Chancellor for Research

Expected recruitment start date

2015-08-27, 1394/06/05

Expected recruitment end date

2015-09-11, 1394/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of levothyroxine in comparison to placebo on thyroid nodule volume in patients with benign thyroid nodule during 1 year follow up

Public title

Assessment of the effect of levothyroxine on benign thyroid nodule volume

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:patiens 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; 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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

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
4193893345

Approval date
2015-08-24, 1394/06/02

Ethics committee reference number
IR.GUMS.REC.1394.210

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, 12 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
control group:using placebo half to one tablet, daily, for 12 months

Category
Placebo

2

Description
intervention group:using levothyroxine with therapeutic dose of 1.8 µg/kg, daily, for 12 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinology Clinic of Razi Hospital

Full name of responsible person
Dr.Ahmad Alizadeh

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
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Associate Professor

Other areas of specialty/work

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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