

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of the effect of Levothyroxine in comparison to placebo on nodule Volume reduction in patients with benign thyroid nodule during six months follow up

Protocol summary

Summary

The purpose of this study is to investigate the effect of Levothyroxine on volume reduction of benign thyroid nodule. A total of 60 patients aged 20-60 years old, with palpable thyroid nodule in physical exam referring to endocrinology subspecialty clinic of Razi hospital, located in Rasht city, are recruited in the study after making sure that the nodule is benign confirmed by FNAB result from the beginning and being in Euthyroid state. Size of nodules are measured by sensitive ultrasound methods, then patients are randomly divided into two groups (intervention and control) using the table of random number distributed. 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 0.1-0.5 mu/l. The control group receives placebo with similar dose. Both groups are followed up for 6 months. Nodule size and TSH serum levels are measured and compared between 2 groups in the beginning and the end of the study. Neither the patient, 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: **IRCT2014030416828N1**

Registration date: **2014-04-24, 1393/02/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-24, 1393/02/04

Registrant information

Name

Saeed Kalantari

Name of organization / entity

Guilan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1723 6186

Email address

dr_skalantari@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences Vice chancellor for research

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-04-19, 1393/01/30

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 nodule Volume reduction in patients with benign thyroid nodule during six months follow up

Public title

Assessment of the effect of Levothyroxine on volume reduction of Benign thyroid nodule

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with single nodule or multi nodules ; that has been proved to be benign with FNA.
Exclusion criteria: age under 20 and over 60 ; history of hypo and hyperthyroidism ; history of using Levothyroxine or other related drugs to thyroid ; pregnancy ; other diseases (cardiovascular or liver disease)

Age

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

Gender

Both

Phase

2-3

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

Guilan University of Medical Sciences Vice chancellor for research

Street address

Guilan University of Medical Sciences Vice chancellor for research , Shahid Sadati st., Namjoo st.

City

Rasht

Postal code

4193893345

Approval date

2014-02-17, 1392/11/28

Ethics committee reference number

1920422811

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 size

Timepoint

begining of assessment - six months later

Method of measurement

Ultrasound

Secondary outcomes

1

Description

TSH

Timepoint

before intervention and 6 weeks later and 6 months later

Method of measurement

laboratory kit

Intervention groups

1

Description

Intervention group:using Levothyroxine with Therapeutic dose of - 1/8 µgr/kg - daily- for six months

Category

Treatment - Drugs

2

Description

Control group : half to one tablet daily for 6 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

Razi Hospital,Sardar Jangal St.

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

Guilan University of Medical Sciences Vice chancellor
for research , Shahid Sadati st., Namjoo st.

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

Sa'eed kalantari

Position

Associate Professor

Other areas of specialty/work**Street address**

Razi Hospital,Sardar Jangal St.

City

Rasht

Postal code

95565541448

Phone

+98 13 1554 1001

Fax**Email**

Dr_skalantari@gums.ac.ir

Web page address**Person responsible for scientific
inquiries****Contact****Name of organization / entity**

Razi hospital

Full name of responsible person

Sa'eed Kalantari

Position

Associate Professor

Other areas of specialty/work**Street address**

Razi Hospital,Sardar Jangal St.

City

Rasht

Postal code**Phone**

+98 13 1554 1001

Fax**Email**

Dr_skalantari@gums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Razi hospital

Full name of responsible person

Hadi Ma'dankar

Position

Radiology resident

Other areas of specialty/work**Street address**

Razi Hospital,Sardar Jangal St.

City

Rasht

Postal code**Phone**

+98 13 1553 5116

Fax**Email**

hadimadankar@gmail.com

Web page address**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