Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effect of Levothyroxine on reduction of benign thyroid nodule's volume in euthyroid patients

Protocol summary

Summary

Thyroid nodules are common and Levothyroxine are used in the treatment of nodules, its impact is still being debated and studies carried out in various countries have reported different results. This study was designed to determine the effect of levothyroxine prescription on decreasing the volume of benign thyroid nodules, in order to determine criteria to predict the effectiveness in each patient and therefore the right choice for patients prescribed levothyroxine, in addition to study the effectiveness in different patients; 132 euthyroid patients with benign thyroid nodule, with the entry conditions were studied and they were divided randomly to two groups; treatment and untreated. The intervention group treated with levothyroxine tab with an initial dose of 1 mcg per kilogram of body weight and dose adjustment created according to TSH levels measured during the period experiments. So, the level of TSH has been in the range MIU / L0.4-0.8. Untreated group uses only the routine cares. Ultrasound was performed for all patients at the beginning as well as 6 and 12 months after starting of the study. Size and specifications of nodules recorded. Finally, results of the two groups were compared and the effectiveness of levothyroxine in reducing the size of benign thyroid nodules as well as effective relation with these criteria (criteria such as the level of TSH, the number of nodules, age, etc.) determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100918858N2**
Registration date: **2016-03-31, 1395/01/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-03-31, 1395/01/12

Registrant information

Name
Masoud Rahmanian

Name of organization / entity
Diabet Research Center, Yazd Shahid Sadughi University Of Mdical Science

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Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University of Medical Sciences
Vice chancellor for research

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Levothyroxine on reduction of benign thyroid nodule's volume in euthyroid patients

Public title

The effect of Levothyroxine on reduction of Thyroid nodule's volume

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1.be euthyroid; 2.non malignant nodule; 3.the age range of 18 to 65 years old. Exclusion criteria:1.treatment with levothyroxin or methimazole; 2.patients of iodine deficiency areas; 3.history of surgery on thyroid; 4.history of head and neck radiation; 5.pregnancy; 6.nodule's cystic portion>20%; 7.heart disease(IHD-arrhythmia); 8.osteoporosis; 9. more than 3 nodules in every thyroid's lobe.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Diabet Research Center, Yazd Shahid Sadoughi Univercity of Medical Science

Street address

Yazd Diabet Research Center, Talar Honar Alley, Shahid Sadoughi Blvd, Yazd

City

Yazd

Postal code

8917693571

Approval date

2014-10-01, 1393/07/09

Ethics committee reference number

17/1/138532

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

Size of thyroid nodules

Timepoint

At the beginnig of the study and after 6 &12 months

Method of measurement

Ultrasonography

2

Description

Volume of thyroid nodule

Timepoint

At the beginnig of the study and after 6 &12 months

Method of measurement

Ultrasonography

Secondary outcomes

1

Description

TSH

Timepoint

At the beginnig of the study; 3 months interval in treatment group and 6 months interval in control group

Method of measurement

Laboratory kit

2

Description

Anti TPO

Timepoint

At the beginnig and the end of the study

Method of measurement

Laboratory kit

3

Description

T4

Timepoint

At the beginnig of the study; 3 months interval in treatment group and 6 months interval in control group

Method of measurement

Laboratory kit

4

Description

T3

Timepoint

At the beginnig of the study; 3 months interval in treatment group and 6 months interval in control group

Method of measurement

Laboratory kit

Intervention groups

1

Description

Intervention group:Levothyroxin1 micro gr/kg daily-peroral and dose modification at lenght of survey

Category

Treatment - Drugs

2

Description

Control group: no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetic Research Center, Yazd Shahid Sadoughi Univercity of Medical Science

Full name of responsible person

Dr. Masoud Rahmanian

Street address

Yazd Diabet Research Center, Talar Honar Alley, Shahid Sadoughi Blvd, Yazd

City

Yazd

2

Recruitment center

Name of recruitment center

Emam Ali clinic

Full name of responsible person

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd Shahid Sadoughi Univercity of Medical Science

Full name of responsible person

Dr. Amir Hooshang Mehrparvar

Street address

Yazd

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd Shahid Sadoughi Univercity of Medical Science

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd Diabet Research Center

Full name of responsible person

Dr. Masoud Rahmanian

Position

Endocrinologist

Other areas of specialty/work

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Name of organization / entity

Diabet Research Center, Yazd Shahid Sadoughi Univercity of Medical Science

Full name of responsible person

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Position

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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