

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The evaluation of the effect of metformin on thyroid benign nodules

Protocol summary

Summary

Objectives: we evaluate the effect of metformin on thyroid nodules volume and size in the present study. Design: Through a placebo-control double blind randomized clinical trial of phase 1, 240 euthyroid women from three endocrine clinics with benign thyroid nodules are selected and classified into four equal groups. Setting and conduct: Thyroid nodule volume is detected by using ellipsoid formula ($\text{length} \times \text{width} \times \text{depth} \times \pi/6$). Levothyroxine dose is adjusted based on serum TSH level, so that TSH is maintained between 0.5-2.5 mU/L and TSH is measured each month. Participants: Euthyroid women with benign thyroid nodules between 0.5-3 cm and TSH between 0.5-2.5 mU/L. Intervention: The first group take metformin 500 mg twice a day and the second group take levothyroxine 100 mcg once a day and the third group take a combination of metformin 500 mg twice a day and levothyroxine 100 mcg once a day for three months. The fourth group don't take any drug during three months. Main outcome measures: Primary outcome variables are the changes of thyroid nodules size. Secondary outcome variables are the changes of thyroid nodules numbers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022325895N3**
Registration date: **2016-12-04, 1395/09/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-04, 1395/09/14

Registrant information

Name

Afsaneh Talaei

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3612

Email address

talaei@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of metformin on thyroid benign nodules

Public title

The effect of metformin on thyroid nodule

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Female sex, benign thyroid nodule with the size of 0.5-3 cm, euthyroid, negative TPO-Ab, TSH between 0.5-2.5 mU/L, lack of chronic disease, lack of drug usage Exclusion criteria: Chronic usage of any kind of drugs more than three months, thyroid cystic nodules, malignant thyroid nodules

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

random permuted blocks

Secondary Ids

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Amiralmomenin Hospital, Baseej Square

City

Arak

Postal code**Approval date**

2013-06-25, 1392/04/04

Ethics committee reference number

92-147-4

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

Thyroid nodule

ICD-10 code

E04.1

ICD-10 code description

Nontoxic single thyroid nodule

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

The changes of thyroid nodule size

Timepoint

The beginning of the study, after three months

Method of measurement

Ultrasonography

Secondary outcomes**1****Description**

The changes of serum TSH level

Timepoint

The beginning of the study, the beginning of the second month, the beginning of the third month, the end of the third month

Method of measurement

Blood test

Intervention groups**1****Description**

Intervention group 1: One tablet of metformin, 500 mg, oral, twice a day, produced by Iran Hormone co, for three months

Category

Treatment - Drugs

2**Description**

Intervention group 2: One tablet of levothyroxine, 0.1 mg, oral, once a day, produced by Iran Hormone co, for three months

Category

Treatment - Drugs

3**Description**

Intervention group 3: Combination of one tablet of metformin, 500 mg, oral, twice a day, produced by Iran Hormone co and one tablet of levothyroxine, 0.1 mg, oral, once a day, produced by Iran Hormone co, for three months

Category

Treatment - Drugs

4**Description**

Control group: Without usage of any drugs for three months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Amiralmomenin Hospital
Full name of responsible person
Afsaneh Talaei
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Mohammad Rafeie
Street address
Arak University of Medical Sciences, Baseej Square
City
Arak

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research, Arak University of Medical Sciences

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
Arak University of Medical Sciences
Full name of responsible person
Afsaneh Talaei
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Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty