Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

The evaluation of the effect of vitamin D on thyroid function in hypothyroid patients

Protocol summary

Summary

Vitamin D deficiency or insufficiency is a common worldwide problem. The association of between hypothyroidism and vitamin D deficiency is controversial. We aimed to evaluate the effect of vitamin D on thyroid function in hypothyroid patients. Through a placebo-double blind randomized clinical trial study, phase 2, 201 hypothyroid patients were recruited from the three endocrinology clinics and are classified into two groups. The patients are stable for more than one year on their levothyroxine dose and TSH level is at 0.5-5 MIU/L without need to change the levothyroxine dose. The patients do not use any other drugs for any diseases. All participants are taken written consent. The demographic data such as age, sex, the presence of goiter, job, and family history of thyroid disease is completed by a questionnaire. At the beginning of the study, serum levels of TSH, T4 and T3 are measured. The patients are randomly characterized into two group; 102 (50.7%) of people in intervention group and 99 (49.3%) of people in the control group. The control group receive placebo addition to levothyroxine and the intervention group take 50000 IU of vitamin D weekly plus to levothyroxine for three months. At the end of three months, the measurement of thyroid hormones including serum TSH, T4 and T3 levels will repeat and the results are compared with the results of the beginning of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022325895N2**
Registration date: **2016-05-29, 1395/03/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-29, 1395/03/09

Registrant information

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Afsaneh Talaei
Name of organization / entity
Arak University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-07-01, 1394/04/10

Expected recruitment end date

2015-09-30, 1394/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of vitamin D on thyroid function in hypothyroid patients

Public title

The effect of vitamin D on hypothyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Controlled hypothyroidism; No need to change the dose of levothyroxine; lack of the other

diseases Exclusion criteria: The presence of other disease; need to change the dose of levothyroxine

Age
From **20 years** old to **57 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **201**

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
Arak University of Medical Sciences

Street address
Arak University of Medical Sciences, Baseej Square, Arak

City
Arak

Postal code
3848176941

Approval date
2015-04-04, 1394/01/15

Ethics committee reference number
93-169-21

Health conditions studied

1

Description of health condition studied
hypothyroidism

ICD-10 code
E03.9

ICD-10 code description
Hypothyroidism, unspecified

Primary outcomes

1

Description
The changes of TSH

Timepoint
the beginning of the study, the end of three months

Method of measurement
Blood sample

2

Description
The changes of T4

Timepoint
the beginning of the study, the end of three months

Method of measurement
Blood sample

3

Description
The changes of T3

Timepoint
the beginning of the study, the end of three months

Method of measurement
Blood sample

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: one tab 50000 per week,oral, for three months

Category
Treatment - Drugs

2

Description
Control: One tab of placebo per week ,oral,for three months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinology Clinic

Full name of responsible person
Afsaneh Talaei

Street address
Amiralmomenin Hospital, Postal Code: 3848176941, Baseej Square, Arak

City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad Rafee
Street address
Health Departmentl, Postal Code:3848176941, Arak University of Medical Sciences, Baseej Square, Arak
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
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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