

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 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

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

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 DepartmentI, 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**

Arak University of Medical Sciences

Full name of responsible person

Afsaneh Talaei

Position

Associate Professor of Endocrinology

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

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

City

Arak

Postal code**Phone**

+98 86 3417 3612

Fax**Email**

afsanehtalaeii@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Afsaneh talaei

Position

Associate Professor of Endocrinology

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

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

City

Arak

Postal code**Phone**

+98 86 3417 3612

Fax**Email**

afsanehtalaeii@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Afsaneh Talaei

Position

Associate Professor of Endocrinology

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

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

City

Arak

Postal code**Phone**

+98 34173630

Fax**Email**

afsanehtalaeii@yahoo.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