

# 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*