

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effect of Vitamin D Replacement on patients with subclinical hypothyroidism: A randomized clinical trial

#### Protocol summary

##### Study aim

The relationship between vitamin D deficiency and subclinical hypothyroidism.

##### Design

a parallel randomized controlled trial, one blind

##### Settings and conduct

The subjects were enrolled in this study from the patients suffering from both subclinical hypothyroidism and Vitamin D deficiency who were referred to Fasa endocrinology clinic (Fasa, Fars, Iran). At first, the information demographic data, past medical history, and laboratory findings was taken from them. The consent inform was filled by patients who met the inclusion criteria. If any subject met exclusion criteria, he or she was eliminated to continue this investigation. They were randomly categorized into two groups of 1 and 2. The subjects do not have any information about the kind of medication.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: The patients suffering from both subclinical hypothyroidism and Vitamin D deficiency.  
Exclusion Criteria: Dissatisfaction to participate in this study The patients with clinical hypothyroidism The patients who take medications that affect thyroid function such as steroid and L-thyroxine The patients with a high level of Thyroid Stimulating Hormone (TSH) >10 mU/L The patients with cardiovascular risk factors, The patients with positive Anti-thyroid peroxidase (anti-TPO) Pregnant women

##### Intervention groups

The subjects were divided into two groups of interventional and control. The interventional group received a vitamin D 50000 unit weekly for 2 months. The control group received the placebo likewise.

##### Main outcome variables

Vitamin D supplement cures the subclinical hypothyroidism and reduces the TSH level. Improving subclinical hypothyroidism can function as a protection against developing subclinical hypothyroidism to clinical

hypothyroidism.

#### General information

##### Reason for update

##### Acronym

TSH

##### IRCT registration information

IRCT registration number: **IRCT20190610043856N1**

Registration date: **2020-03-17, 1398/12/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-17, 1398/12/27**

Update count: **0**

##### Registration date

2020-03-17, 1398/12/27

##### Registrant information

##### Name

Ali Ahmadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3631 4683

##### Email address

a.ahmadi@fums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-01, 1398/10/11

##### Expected recruitment end date

2021-01-05, 1399/10/16

##### Actual recruitment start date

2020-01-12, 1398/10/22

##### Actual recruitment end date

2021-01-19, 1399/10/30

**Trial completion date**

2021-01-20, 1399/11/01

**Scientific title**

The effect of Vitamin D Replacement on patients with subclinical hypothyroidism: A randomized clinical trial

**Public title**

The effect of vitamin D replacement on patients with subclinical hypothyroidism

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Subclinical Hypothyroidism Vitamin D Deficiency

**Exclusion criteria:**

Vitamin D replacement therapy in the last 15 months  
Overt hypothyroidism Those taking medications that affect thyroid function such as steroid and L-thyroxine  
Patients with symptoms of hypothyroid, Cardiovascular risk factors, Positive TPO antibody Abnormal T4 Pregnant women TSH >10 mIU/l

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **75**

More than 1 sample in each individual

Number of samples in each individual: **2**

One sample for vit D and one sample for Tsh

Actual sample size reached: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The participants of the study were allocated to study groups through pure chance, namely, random allocation. The method of randomization was simple; that is, each of the individual patients was randomly allocated to the intervention or control group by the use of table of random numbers. Allocation concealment was carried out; that is, the participants were not made aware of the groups to which they belonged.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Three groups were blinded in this study: first of all, the patients who took part in this study had no idea about their group allocation and the treatment or placebo they received. Second, care providers were also blinded in this study. They were not informed of the group allocations. Nor did they have any information about the treatment or placebo each group received. Finally, the data analyser was blinded in the study; that is, he was not informed of the nature of data, the groups and the

treatment/placebo.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Fasa University of Medical Science

**Street address**

Vali-e-Asr Hospital, Fasa University of Medical Science, Ibn Sina Square, Fasa, Fars

**City**

Fasa

**Province**

Fars

**Postal code**

7461686688

**Approval date**

2018-12-07, 1397/09/16

**Ethics committee reference number**

IR.FUMS.REC.1397.115

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

Subclinical Hypothyroidism

**ICD-10 code**

E02

**ICD-10 code description**

Subclinical iodine-deficiency hypothyroidism

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

Thyroid stimulating hormone (TSH) between 5 to 10 mU/L

**Timepoint**

Thyroid-stimulating hormone (TSH) measurement at baseline (before intervention) and 2 months after the intervention.

**Method of measurement**

Enzyme Linked Fluorescence Assay

**2****Description**

Vitamin D deficiency

## Timepoint

Vitamin D measurement at baseline (before intervention) and 2 months after the intervention.

## Method of measurement

Enzyme Linked Flourscience Assay

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: They did not receive vitamin D.

#### Category

Placebo

### 2

#### Description

Intervention group: the participants of this group were treated through pearls of vitamin D, produced by Zahravi Pharmacy Co., with 50000 units weekly for two months.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Fasa Endocrinology clinic

##### Full name of responsible person

Ali Ahmadi

##### Street address

Ibn Sina Square

##### City

Fasa

##### Province

Fars

##### Postal code

7461686688

##### Phone

+98 71 3631 4683

##### Email

a.ahmadi@fums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Fasa University of Medical Sciences

##### Full name of responsible person

Mojtaba Farjam

##### Street address

Ibn Sina Square

##### City

Fasa

##### Province

Fars

##### Postal code

7461686688

##### Phone

+98 71 5331 6300

##### Fax

+98 71 5331 6300

##### Email

a.ahmadi@fums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Fasa University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Fasa University of Medical Sciences

##### Full name of responsible person

Ali Ahmadi

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Internal Medicine

##### Street address

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##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Fasa University of Medical Sciences

**Full name of responsible person**

Ali Ahmadi

**Position**

Residency

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Most of the data can be shared after publication of the manuscript.

**When the data will become available and for how long**

One year after publication

**To whom data/document is available**

Academic Institutions

**Under which criteria data/document could be used**

no other criteria

**From where data/document is obtainable**

a.ahmadi1346@yahoo.com

**What processes are involved for a request to access data/document**

a.ahmadi1346@yahoo.com

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

Ali Ahmadi

**Position**

Residency

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

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