Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Ibn Sina Square
City
Fasa
Province
Fars
Postal code
7186664988
Phone
+98 71 3631 4683
Email
a.ahmadi@fums.ac.ir

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
Street address
Ibn Sina Square
City
Fasa
Province
Fars
Postal code
7186664988
Phone
+98 71 3631 4683
Email
a.ahmadi@fums.ac.ir

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
Street address
Ibn Sina Square
City
Fasa
Province
Fars
Postal code
7186664988
Phone
+98 71 3631 4683
Email
a.ahmadi@fums.ac.ir

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