Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of vitamin B1 on thyroid hormones and lipid profile of patients with hypothyroidism receiving levothyroxine

Protocol summary

Study aim
Determining the effect of vitamin B1 on thyroid hormones and lipid profile of patients with hypothyroidism before and after intervention

Design
This before-and-after semi-experimental study will be conducted on 49 patients with hypothyroidism between the ages of 30 and 50 years with TSH values greater than 10 µIU/mL, T4 less than 4 ng/dL, and serum Anti-TPO levels greater than 200 U/mL with a diagnosis of hypothyroidism.

Settings and conduct
Endocrinology Clinic of Dezful's Ganjaviyan Hospital in the spring and summer of 1404

Participants/Inclusion and exclusion criteria
Patients with hypothyroidism between the ages of 30 and 50 years with TSH values greater than 10 µIU/mL, T4 less than 4 ng/dL, and serum Anti-TPO levels greater than 200 U/mL will be enrolled in the study with a diagnosis of hypothyroidism.

Intervention groups
Patients will receive the usual treatment for hypothyroidism (levothyroxine) and in addition to levothyroxine, they will also receive a 300 mg vitamin B1 tablet daily in the morning before breakfast and half an hour to 1 hour before taking levothyroxine.

Main outcome variables
Thyroxine (T4) hormone; Thyroid-stimulating hormone (TSH); Serum anti-TPO; Serum total cholesterol (TC); Serum LDL-C; Serum HDL-C; LDL-C to HDL-C ratio; Serum triglyceride (TG); Serum VLDL; Atherogenic index.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250502065563N1**
Registration date: **2025-08-03, 1404/05/12**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-03, 1404/05/12**
Update count: **0**

Registration date
2025-08-03, 1404/05/12

Registrant information

Name
Ali Akbar Oroojan
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 4242 9533
Email address
aliakbar_oroojan@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-22, 1404/04/01

Expected recruitment end date
2025-08-23, 1404/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of vitamin B1 on thyroid hormones and lipid profile of patients with hypothyroidism receiving levothyroxine

Public title
The effect of vitamin B1 on patients with hypothyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with hypothyroidism The ages between 30 and 50 years old TSH levels greater than 10 µIU/mL T4 levels less than 4 ng/dL Serum Anti-TPO levels greater than 200 U/mL

Exclusion criteria:

History of thyroid surgery Thyroid malignancies Hypothyroidism resulting from hyperthyroidism treatment Other known autoimmune and rheumatic diseases Renal failure and malabsorption History of use of antithyroid drugs History of use of cytotoxics History of use of immunosuppressants History of use of immunomodulators History of use of glucocorticoids History of use of amiodarone, lithium, interferon, radioiodine, History of chemotherapy History of use of supplements containing vitamin B1 pregnancy

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **49**

More than 1 sample in each individual

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

Two blood samplings are performed at the beginning and end of the study to check hormonal and lipid variables.

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Dezful University of Medical Sciences

Street address

Dezful, end of Azadegan Boulevard, next to the Traffic Department

City

Dezful

Province

Khouzestan

Postal code

6461653476

Approval date

2025-05-13, 1404/02/23

Ethics committee reference number

IR.DUMS.REC.1404.004

Health conditions studied

1

Description of health condition studied

Hypothyroidism

ICD-10 code

E03

ICD-10 code description

Other hypothyroidism

Primary outcomes

1

Description

Thyroxine hormone (T4)

Timepoint

Before the start of the study and 1 month and 2 months after starting to take vitamin B1 tablets

Method of measurement

Blood collection from the patient and serum separation

2

Description

Thyroid-stimulating hormone (TSH)

Timepoint

Before the start of the study and 1 month and 2 months after starting to take vitamin B1 tablets

Method of measurement

Blood collection from the patient and serum separation

3

Description

serum Anti-TPO

Timepoint

Before the start of the study and 1 month and 2 months after starting to take vitamin B1 tablets

Method of measurement

Blood collection from the patient and serum separation

Secondary outcomes

1

Description

Serum total cholesterol (TC)

Timepoint

Before the start of the study and 1 and 2 months after receiving vitamin B1 tablets

Method of measurement

Blood collection and serum separation from the patient

2

Description
Serum LDL-C
Timepoint
Before the start of the study and 1 and 2 months after receiving vitamin B1 tablets
Method of measurement
Blood collection and serum separation from the patient

3

Description
Serum HDL-C
Timepoint
Before the start of the study and 1 and 2 months after receiving vitamin B1 tablets
Method of measurement
Blood collection and serum separation from the patient

4

Description
LDL-C to HDL-C ratio
Timepoint
Before the start of the study and 1 and 2 months after receiving vitamin B1 tablets
Method of measurement
Blood collection and serum separation from the patient

5

Description
Serum triglycerides (TG)
Timepoint
Before the start of the study and 1 and 2 months after receiving vitamin B1 tablets
Method of measurement
Blood collection and serum separation from the patient

6

Description
Serum VLDL
Timepoint
Before the start of the study and 1 and 2 months after receiving vitamin B1 tablets
Method of measurement
Blood collection and serum separation from the patient

7

Description
Atherogenic index
Timepoint
Before the start of the study and 1 and 2 months after receiving vitamin B1 tablets
Method of measurement
Blood collection and serum separation from the patient

Intervention groups

1

Description
In the present before-and-after semi-experimental study, 49 patients with hypothyroidism between the ages of 30 and 50 years with TSH levels greater than 10 µIU/mL and T4 less than 4 ng/dL and serum Anti-TPO levels greater than 200 U/mL will be enrolled in the study with a diagnosis of hypothyroidism. Patients will receive the usual treatment for hypothyroidism, namely levothyroxine, and in the intervention group, in addition to levothyroxine, they will receive 300 mg of vitamin B1 tablet daily in the morning on an empty stomach and half to 1 hour before taking levothyroxine. The duration of the treatment period is 2 months. After the end of 2 months of treatment, blood samples will be taken from the patients and the variables of TSH, T4, Anti-TPO, TG, TC, LDL-C, HDL-C, and VLDL in the patients' serum will be measured. On the other hand, the LDL-C/HDL-C ratio and the atherogenic index will be calculated based on the formula (TG/HDL-C) log.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology Clinic, Ganjovian Hospital, Dezful
Full name of responsible person
Vali Moradi
Street address
At the beginning of the Dezful-Andimeshk road, opposite the 292nd Armored Brigade
City
Dezful
Province
Khouzestan
Postal code
6461653476
Phone
+98 61 4242 9533
Email
aliakbar_oroojan@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dezfoul University of Medical Sciences
Full name of responsible person
Dr. Mohammad Amin Behmanesh
Street address
Dezful, end of Azadegan Boulevard, next to the Traffic Department
City
Dezful
Province

Khouzestan
Postal code
6461653476
Phone
+98 61 4242 9533
Email
aliakbar_oroojan@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dezfoul 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
Dezfoul University of Medical Sciences
Full name of responsible person
Ali Akbar Oroojan
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Dezful, end of Azadegan Boulevard, next to the Traffic Department, New Medical School, Faculty of Education Vice Chancellor's Office
City
Dezful
Province
Khouzestan
Postal code
6461653476
Phone
+98 61 4242 9533
Fax
Email
aliakbar_oroojan@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Dezfoul University of Medical Sciences
Full name of responsible person
Ali Akbar Oroojan
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Dezful, end of Azadegan Boulevard, next to the Traffic Department, New Medical School, Faculty of Education Vice Chancellor's Office
City
Dezful
Province
Khouzestan
Postal code
6461653476
Phone
+98 61 4242 9533
Fax
Email
aliakbar_oroojan@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Dezfoul University of Medical Sciences
Full name of responsible person
Ali Akbar Oroojan
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Province
Khouzestan
Postal code
6461653476
Phone
+98 61 4242 9533
Fax
Email
aliakbar_oroojan@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
In accordance with the principles of publishing and writing articles for this category of studies, the results of this study can be published as an average in the resulting article and will not be published individually.
Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some data, such as information related to the main outcome and the results of laboratory analyses performed, can be shared.

When the data will become available and for how long

After the article is published

To whom data/document is available

The data results will be published in the paper from the current study and will be visible to all researchers.

Under which criteria data/document could be used

Documentation for the implementation and conduct of future studies by researchers is available in the form of a printed article, which will also be made available to the Vice President for Education, Research, and Technology of the university.

From where data/document is obtainable

Vice President for Education, Research and Technology Contact Number: 00986142429533 Zip Code: 6461653476

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

A formal letter of request should be sent to the Vice Chancellor for Education, Research and Technology of Dezful University of Medical Sciences and they will receive their official response. This process takes approximately 1 month.

Comments