# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Evaluation of the effect of taurine in patients with hyperthyroidism treated with methimazole: A two-group randomized placebo-controlled clinical trial

## Protocol summary

**Study aim**

To evaluate the effects of taurine supplementation alongside methimazole on anxiety, sleep quality, fatigue, cortisol levels, thyroid hormones, blood pressure, heart rate, liver enzymes, and hematological parameters in patients with hyperthyroidism.

**Design**

This is a randomized, double-blind, placebo-controlled, parallel-group clinical trial involving 60 patients allocated in a 1:1 ratio using variable block randomization. Participants and outcome assessors will be blinded. Assessments will be conducted at baseline and after the four-week intervention.

**Settings and conduct**

The study will be conducted at a private endocrinology clinic in Dezful. Sixty patients will be recruited through consecutive sampling and randomly allocated to intervention and control groups after four weeks of methimazole stabilization. Taurine or placebo will be administered for four weeks, with assessments performed before and after the intervention.

**Participants/Inclusion and exclusion criteria**

Participants will include patients aged 18–60 years with clinically and laboratory-confirmed hyperthyroidism who have received methimazole at a daily dose of 10–20 mg for at least four weeks, are able to complete questionnaires, and provide informed consent. Proposed exclusion criteria include pregnancy and severe hepatic, renal, or cardiac disease at screening.

**Intervention groups**

Intervention group (n=30): Participants will receive oral taurine capsules at a dose of 500 mg once daily, 1–2 hours before bedtime, for four consecutive weeks, in addition to standard methimazole therapy at a daily dose of 10–20 mg. The intervention will begin after at least four weeks of methimazole treatment.

**Main outcome variables**

The primary outcome is the change in anxiety score measured using the 7 items Generalized Anxiety Disorder questionnaire at baseline and after four weeks of intervention, with changes compared between the two groups

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20250502065563N4**
Registration date: **2026-10-31, 1405/08/09**
Registration timing: **prospective**

Last update: **2026-10-31, 1405/08/09**
Update count: **0**

**Registration date**

2026-10-31, 1405/08/09

**Registrant information**

**Name**

Ali Akbar Oroojan

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 61 4242 9533

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**Recruitment status**

**Not yet recruiting**

**Funding source**

**Expected recruitment start date**

2026-12-22, 1405/10/01

**Expected recruitment end date**

2027-12-22, 1406/10/01

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluation of the effect of taurine in patients with hyperthyroidism treated with methimazole: A two-group randomized placebo-controlled clinical trial

**Public title**
Effect of taurine in patients with hyperthyroidism
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age between 18 and 60 years. Clinically and laboratory-confirmed hyperthyroidism. Receiving methimazole at a daily dose of 10–20 mg. At least four weeks since initiation of methimazole treatment. No use of taurine or other amino acid supplements during the previous four weeks. No regular use of sedatives, hypnotics, or medications affecting the central nervous system. Ability to complete the study questionnaires. Provision of written informed consent.
**Exclusion criteria:**
Presence of severe liver, kidney or heart disease at screening. Pregnancy at screening.
**Age**
From **18 years** old to **60 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **1**
Collection of 5 cc of blood at two time points: at the beginning and at the end of the study.
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, 60 eligible patients will be randomly allocated in a 1:1 ratio to the intervention and control groups after obtaining informed consent and completing methimazole stabilization. The unit of randomization will be the individual patient. An independent individual will generate the random allocation sequence using computer-generated random numbers. Variable block randomization will be used. No stratification is planned. The allocation list will remain confidential, and group assignments must be concealed from the person enrolling participants until each patient is assigned.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Participants, outcome assessors, and the statistical analyst will be blinded to treatment allocation. Taurine and placebo capsules will be identical in appearance, color, size, and packaging and will be coded. Allocation codes will remain confidential until completion of the final data analysis.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Dezful University of Medical Sciences
**Street address**
Khuzestan Province, Dezful, End of Azadegan Boulevard, Next to the Traffic Police Department, Iran
**City**
Dezful
**Province**
Khouzestan
**Postal code**
6461653476
**Approval date**
2026-10-07, 1405/07/15
**Ethics committee reference number**
IR.DUMS.REC.1405.072

## Health conditions studied

### 1

**Description of health condition studied**
Hyperthyroidism
**ICD-10 code**
E05
**ICD-10 code description**
Thyrotoxicosis [hyperthyroidism]

## Primary outcomes

### 1

**Description**
The primary outcome is the change in anxiety score measured using the seven-item Generalized Anxiety Disorder questionnaire at baseline and after four weeks of intervention, with changes compared between the two groups.

**Timepoint**
At baseline and at the end of the fourth week of intervention.
**Method of measurement**
The seven-item Generalized Anxiety Disorder questionnaire, with scores ranging from 0 to 21; higher scores indicate greater anxiety severity.

## Secondary outcomes

### 1

**Description**
Change in sleep quality score assessed using the Pittsburgh Sleep Quality Index
**Timepoint**
At baseline and at the end of the fourth week of intervention.
**Method of measurement**
Pittsburgh Sleep Quality Index questionnaire, with scores ranging from 0 to 21; higher scores indicate poorer sleep quality.

### 2

**Description**
Change in mean fatigue severity score assessed using the Fatigue Severity Scale
**Timepoint**
At baseline and at the end of the fourth week of intervention.
**Method of measurement**
Fatigue Severity Scale consisting of nine items rated on a seven-point scale; the final score is the mean of the nine item scores.

### 3

**Description**
Change in serum cortisol concentration
**Timepoint**
At baseline and at the end of the fourth week, between 7:00 and 9:00 AM.
**Method of measurement**
Measurement of serum cortisol concentration after 8–12 hours of fasting using the enzyme-linked immunosorbent assay or a standard laboratory method.

### 4

**Description**
Changes in serum thyroid-stimulating hormone, free thyroxine, and triiodothyronine levels
**Timepoint**
At baseline and at the end of the fourth week of intervention.
**Method of measurement**
Measurement of serum thyroid hormone concentrations using the enzyme-linked immunosorbent assay.

### 5

**Description**
Changes in systolic and diastolic blood pressure
**Timepoint**
At baseline and at the end of the fourth week of intervention.
**Method of measurement**
Measurement of systolic and diastolic blood pressure using a calibrated digital blood pressure monitor after at least five minutes of seated rest. The mean of two consecutive measurements will be recorded in millimeters of mercury.

### 6

**Description**
Change in heart rate measured in beats per minute
**Timepoint**
At baseline and at the end of the fourth week of intervention.
**Method of measurement**
Measurement of heart rate using a calibrated digital blood pressure monitor after at least five minutes of seated rest.

### 7

**Description**
Changes in serum alanine aminotransferase and aspartate aminotransferase activities
**Timepoint**
At baseline and at the end of the fourth week of intervention.
**Method of measurement**
Measurement of liver enzyme activities using standard enzymatic colorimetric assays and an automated biochemistry analyzer.

### 8

**Description**
Changes in complete blood count parameters
**Timepoint**
At baseline and at the end of the fourth week of intervention.
**Method of measurement**
Measurement of complete blood count parameters using an automated hematology analyzer.

### 9

**Description**
Change in serum C-reactive protein concentration
**Timepoint**
At baseline and at the end of the fourth week of intervention.
**Method of measurement**
Measurement of serum C-reactive protein concentration using a standard laboratory assay.

## Intervention groups

### 1

**Description**

Intervention group (n=30): Participants will receive oral taurine capsules at a dose of 500 mg once daily, 1–2 hours before bedtime, for four consecutive weeks, in addition to standard methimazole therapy at a daily dose of 10–20 mg. The intervention will begin after at least four weeks of methimazole treatment.

**Category**

Treatment - Drugs

**2**

**Description**

Control group (n=30): Participants will receive methimazole at a daily dose of 10–20 mg along with placebo capsules identical to taurine in appearance, color, size, and packaging. The placebo will be administered once daily, 1–2 hours before bedtime, for four consecutive weeks.

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Private Endocrinology and Metabolism Clinic, Dezful, Iran

**Full name of responsible person**

Hamid Karimi

**Street address**

Neshat 1 Medical Complex, Taleghani Street, Dezful, Iran.

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**Email**

Karimi.h@dums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Dezfoul University of Medical Sciences

**Full name of responsible person**

Abbas Heidarimoghadam

**Street address**

Next to the Traffic Police Department, End of Azadegan Boulevard, Dezful, Khuzestan Province, Iran.

**City**

Dezful

**Province**

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**Phone**

+98 61 4242 2710

**Email**

research.dums@gmail.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

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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## 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**

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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**

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