Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation of the Effect of Glycine in Patients with Hyperthyroidism Treated with Methimazole: A Two-Arm, Placebo-Controlled, Randomized Clinical Trial

Protocol summary

Study aim

To evaluate the effects of glycine supplementation alongside methimazole on anxiety, sleep quality, fatigue severity, cortisol levels, thyroid hormones, cardiovascular parameters, liver function, and hematological indices 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 the private endocrinology clinic of a faculty member of Dezful University of Medical Sciences. Patients will be recruited through consecutive sampling.

Participants/Inclusion and exclusion criteria

Participants will include patients aged 18–60 years with clinically and laboratory-confirmed hyperthyroidism who have received methimazole (10–20 mg daily) for at least four weeks and provided informed consent. Proposed exclusion criteria include pregnancy and severe hepatic, renal, or cardiac disease at screening.

Intervention groups

Intervention group (n=30): Oral glycine 1 g daily plus methimazole (10–20 mg daily). Control group (n=30): Matching placebo plus methimazole. Glycine or placebo will be administered once daily, 1–2 hours before bedtime, for four weeks.

Main outcome variables

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.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250502065563N3**
Registration date: **2026-10-16, 1405/07/24**
Registration timing: **prospective**

Last update: **2026-10-16, 1405/07/24**
Update count: **0**

Registration date

2026-10-16, 1405/07/24

Registrant information

Name

Ali Akbar Oroojan

Name of organization / entity

Country

Iran (Islamic Republic of)

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+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
Investigation of the Effect of Glycine in Patients with Hyperthyroidism Treated with Methimazole: A Two-Arm, Placebo-Controlled, Randomized Clinical Trial

Public title
The effect of glycine in patients with hyperthyroidism

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 and 60 years. Clinically and laboratory-confirmed diagnosis of hyperthyroidism. Receiving methimazole treatment at a daily dose of 10–20 mg. At least four weeks since initiation of methimazole treatment. Ability to complete the study questionnaires. Provision of written informed consent to participate in the study.

Exclusion criteria:
Presence of severe liver, kidney and heart disease at the time of screening. Pregnancy at the time of screening and prior to study entry.

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: **2**
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 the methimazole stabilization period. The unit of randomization will be the individual patient. Randomization will be performed using variable block sizes. An independent individual, not involved in trial implementation, will generate the random allocation sequence using computer-generated random numbers. The allocation list will remain confidential, and allocation concealment will be maintained to prevent the person enrolling participants from knowing upcoming assignments.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants, outcome assessors, and the statistical analyst will be blinded to treatment allocation. Glycine 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
School of Medicine, Dezful University of Medical Sciences, Azadegan Street, Dezful, Iran.

City
Dezful

Province
Khouzestan

Postal code
6461653476

Approval date
2026-10-07, 1405/07/15

Ethics committee reference number
IR.DUMS.REC.1405.071

Health conditions studied

1

Description of health condition studied
Hyperthyroidism

ICD-10 code
E05

ICD-10 code description
Thyrotoxicosis [hyperthyroidism]

Primary outcomes

1

Description
Change in anxiety score assessed using the seven-item Generalized Anxiety Disorder questionnaire

Timepoint
At baseline, before the intervention, and at the end of the fourth week after initiation of glycine or placebo administration.

Method of measurement
The seven-item Generalized Anxiety Disorder questionnaire, with a total score ranging from 0 to 21, where 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 a total score 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 calculated as 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 using the enzyme-linked immunosorbent assay or the standard method employed by the central laboratory.

4

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.

5

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

6

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.

7

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.

8

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.

9

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 mmHg.

Intervention groups

1

Description
Intervention group: Participants in this group (n=30) will receive oral glycine supplementation at a dose of 1 gram 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 as prescribed by their physician. Supplementation will begin at least four weeks after initiation of methimazole treatment.
Category
Treatment - Drugs

2

Description
Control group: Participants in this group (n=30) will receive standard methimazole therapy at a daily dose of 10–20 mg as prescribed by their physician. They will also receive an oral placebo matched to glycine in appearance, color, size, and packaging, 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 University of Medical Sciences, Dezful, Iran
Full name of responsible person
Hamid Karimi
Street address
1st Floor, Neshat 1 Medical Complex, Neshat Street, Taleghani Street, Dezful, Iran
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Postal code
6461796455
Phone
+98 61 4225 2840
Email
Karim.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
Khuzestan Province, Dezful, End of Azadegan Boulevard, Next to the Traffic Police Department, Iran.
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Khouzestan
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6461653476
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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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
There is no further information.
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