

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### The effects of hot-tempered diet on signs, symptoms and serum thyroid hormones level in Symptomatic but euthyroid hypothyroid patients treated with levothyroxine.

#### Protocol summary

##### Study aim

Determining the effect of hot-tempered diet, based on traditional medicine reference texts, on the signs and symptoms and level of thyroid hormones in patients with symptomatic euthyroid hypothyroidism treated with levothyroxine.

##### Design

The treatment group with a sample size of 49 people will be selected from among the patients referred to the internal clinic. People will be given a warm diet based on traditional medicine and will be blinded about the type of diet they receive. Patients' nutritional status is checked at the beginning and every three days in the form of food frequency. The Zolowski clinical questionnaire is completed at the first visit and the necessary tests are performed on the first day of the visit. Patients are required to follow a diet for 6 weeks. After that, they will be re-visited and completed the Zolowski questionnaire and re-tested.

##### Settings and conduct

After informed consent has been accepted, eligible patients are examined and Zulewski score will be determined, also serum levels of TSH, total T3, ALT and creatinin will be also measured. Then, specific diet will be taught to individual. After six weeks the patient will be re-visited and the initial questionnaire will be completed again and the serum levels of TSH, total T3 and ALT and creatinin will be checked again.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: hypothyroid patients, aged 18 to 65 y/o who have been treated with levothyroxine with normal TSH in the last 3 months and have a Zulewski score > 3 on examination. Exclusion criteria: pregnancy; chronic diseases; change in drug dose during the study, Non-compliance with the diet, at least 70% based on the form of food frequency.

##### Intervention groups

The intervention is change diet to hot-tempered for 6 weeks. This diet change, will be after educating to patients.

##### Main outcome variables

Zulewski score; serum level of TSH; T3; ALT and creatinine

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220608055102N1**

Registration date: **2022-06-13, 1401/03/23**

Registration timing: **prospective**

Last update: **2022-06-13, 1401/03/23**

Update count: **0**

##### Registration date

2022-06-13, 1401/03/23

##### Registrant information

##### Name

Ali Azizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3324 4052

##### Email address

ali.azizi.bh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-01, 1401/04/10

##### Expected recruitment end date

2022-10-22, 1401/07/30  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The effects of hot-tempered diet on signs, symptoms and serum thyroid hormones level in Symptomatic but euthyroid hypothyroid patients treated with levothyroxine.

**Public title**  
The effect of hot-tempered diet on the signs and symptoms and levels of thyroid hormones

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Hypothyroid patients have been treated with levothyroxine. Patients who have had normal TSH(5-5/0) in the last 3 months. Zulewski score Zulewski score > 3.  
**Exclusion criteria:**  
Pregnancy. Hypothyroidism caused by surgery or radioactive iodine. Chronic diseases such as diabetes mellitus. Dose changing of levothyroxine during the study. Taking interfering drugs with thyroid tests. Diseases of the hypothalamus and pituitary gland.

**Age**  
From **18 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Care provider
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **49**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
In this study, all patients before and after receiving the diet were examined for the Zulewski score and serum levels of TSH and Total T3 were measured; Since the scoring is filled out by the clinic doctor, the examiner is unaware of the study and the reason behind the examination.

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Isfahan, Hezar Jerib St., Isfahan University of Medical Sciences, Building No. 3, School of Medicine, Ground Floor, Department of Medical Ethics

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2020-11-29, 1399/09/09

#### Ethics committee reference number

IR.MUI.MED.REC.1399.764

## Health conditions studied

### 1

#### Description of health condition studied

Hypothyroidism

#### ICD-10 code

E03.9

#### ICD-10 code description

Hypothyroidism, unspecified

## Primary outcomes

### 1

#### Description

Zulewski score

#### Timepoint

At the beginning and 6 weeks later

#### Method of measurement

Zulewski questionnaire

### 2

#### Description

Thyroid stimulating hormone serum level

#### Timepoint

At the beginning and 6 weeks later

#### Method of measurement

Laboratory

### 3

#### Description

Triiodothyronine serum level

**Timepoint**

At the beginning and 6 weeks later

**Method of measurement**

Laboratory

**4****Description**

Alanine transaminase serum level

**Timepoint**

At the beginning and 6 weeks later

**Method of measurement**

Laboratory

**5****Description**

Creatinine serum level

**Timepoint**

At the beginning and 6 weeks later

**Method of measurement**

Laboratory

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Each person is given dietary measures based on traditional Iranian medicine, which are classified as hot and cold temperament. These recommendations include eliminating cold-tempered foods and consuming hot-tempered foods. Patients are asked to complete the food frequency form twice a week, which will be reviewed at the next visit. Any patient who follows less than 70% of the recommendations Has been removed from the study. Educating each patient during the first visit is to explain the reason and method of study, a list of hot and cold foods, giving a sufficient number of food frequency forms and the contact number of the support doctor for emergencies.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Amin Hospital

**Full name of responsible person**

Mohammad Shirzadi

**Street address**

Ebn-e-Sina St., Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

5314181486

**Phone**

+98 31 3445 5051

**Email**

amin@mui.ac.ir

**Web page address**

http://amin.mui.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mojgan Mortazavi

**Street address**

Hezar Jarib Ave.

**City**

isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 8134

**Email**

vcr-office@med.mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Shirzadi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine  
**Street address**  
Alzahra hospital, Shohada e Soffe Ave.  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
81746  
**Phone**  
+98 31 3620 1274  
**Email**  
omid.shirzadi@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Mohammad Shirzadi  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Internal Medicine  
**Street address**  
Alzahra hospital, Shohada e Soffe Ave.  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
81746  
**Phone**  
+98 31 3620 1274  
**Email**  
omid.shirzadi@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Mohammad Shirzadi  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Internal Medicine  
**Street address**

Alzahra hospital, Shohada e Soffe Ave.  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
81746  
**Phone**  
+98 31 3620 1274  
**Email**  
omid.shirzadi@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

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

Deidentified individual participant data collected for the primary and secondary outcome measures will be shared if necessary.

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

Starting 6 months after publication.

### To whom data/document is available

The data will be available for physicians working in academic institutions and also clinicians working in the field of internal medicine.

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

The raw data and results of this study can be used in future relevant systematic reviews. Thus, the raw data and results of this study will be available for researchers working in the field of internal medicine.

### From where data/document is obtainable

Applicants can contact Dr. Mohammad Shirzadi by email. Email address: [omid.shirzadi@gmail.com](mailto:omid.shirzadi@gmail.com)

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

Applicants should explain in detail about their project and how the data/documents of this study will be used in their project. Then, the data/documents files will be sent by email to applicants on request. This process may take 10-12 working days.

### Comments