

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Efficacy of ginger in control of resistant symptom in hypothyroid patient's under thyroid hormone replacement treatment

#### Protocol summary

##### Study aim

Determination of the effect of ginger diet on refractory symptoms in patients with hypothyroidism

##### Design

A randomized, double-blind, placebo-controlled clinical trial

##### Settings and conduct

Sixty hypothyroid patients and 60 normal TSH population with inclusion criteria were divided into two groups of 30 with A and B using block 4 randomization method. Demographic information is recorded. Blood samples are taken for TG, CHOL, FBS, TSH tests. ThySRQ questionnaire is completed for all patients. Group A and C were then given ginger capsules (500 mg twice daily) and group B and D received placebo capsules for one month. After one month of treatment, each patient is re-evaluated by performing ThySRQ tests and recording data.

##### Participants/Inclusion and exclusion criteria

A patient with controlled thyroid dysfunction, who still complains of symptoms Serum TSH level should be between .5 -5 units Informed consent of patients to participate in the study Age range 20-60 years Body mass index 19-35. Pregnancy 2. Co-infection with other thyroid diseases 3. Any type of malignancy 4. Experience the courage of ginger 5. Liver and kidney failure 6. Diseases related to the hypothalamic pituitary pathway 7. With malabsorption disorders such as celiac disease, IBD, atrophic gastritis 8. Concomitant use of drugs such as phenobarbital, phenytoin, carbamazepine, rifampin, glucocorticoid, estrogen, raloxifene 9- caused by severe mental illness 10- Use warfarin and statins 11. Purpose of pregnancy

##### Intervention groups

We have two groups of 60 low-functioning thyroid and a normal population, each divided into two subgroups of 30 each, given one capsule group containing ginger powder and the other with a placebo

##### Main outcome variables

Help control resistant symptoms in hypothyroid patients undergoing thyroid hormone replacement therapy, such as feeling weak, coldness, menstrual disorders, constipation, depression ...

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191231045961N1**

Registration date: **2020-02-06, 1398/11/17**

Registration timing: **prospective**

Last update: **2020-02-06, 1398/11/17**

Update count: **0**

##### Registration date

2020-02-06, 1398/11/17

##### Registrant information

##### Name

hamide ashraf

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3323 3667

##### Email address

stud2391929048@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-17, 1399/01/29

##### Expected recruitment end date

2020-08-21, 1399/05/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Efficacy of ginger in control of resistant symptom in hypothyroid patient's under thyroid hormone replacement treatment

**Public title**

The effect of ginger on hypothyroidism

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

A patient with controlled thyroid dysfunction, who still complains of symptoms Serum TSH level should be between .5 -5 units Informed consent of patients to participate in the study Age range 20-60 years Body mass index 19-35

**Exclusion criteria:**

Pregnancy 2. Co-infection with other thyroid diseases 3. Any type of malignancy 4. Experience the courage of ginger 5. Liver and kidney failure 6. Diseases related to the hypothalamic pituitary pathway 7. With malabsorption disorders such as celiac disease, IBD, atrophic gastritis 8. Concomitant use of drugs such as phenobarbital, phenytoin, carbamazepine, rifampin, glucocorticoid, estrogen, raloxifene 9- caused by severe mental illness 10- Use warfarin and statins 11. Purpose of pregnancy

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using a block size 4 block randomization method based on the list provided by Random Allocation software separately for each patient group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The placebo is given to participants in a color and drug-like odor scheme, and none of the dispensing personnel, the laboratory, and the co-worker except the principal therapist know that each patient received the drug or the medication.

**Placebo**

Used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz university of Medical Sciences

**Street address**

Zand Boulevard, Imam Hussein Square, School of Medicine

**City**

Shiraz

**Province**

Fars

**Postal code**

7134845794

**Approval date**

2020-01-07, 1398/10/17

**Ethics committee reference number**

IR.SUMS.MED.REC.1398.548

**Health conditions studied****1****Description of health condition studied**

Hypothyroidism

**ICD-10 code**

E03

**ICD-10 code description**

Other hypothyroidism

**Primary outcomes****1****Description**

Symptoms of refractory symptoms in hypothyroid patients

**Timepoint**

Baseline and one month after treatment

**Method of measurement**

ThySRQ questionnaire

**Secondary outcomes****1****Description**

TSH

**Timepoint**

At baseline and after one month  
**Method of measurement**  
chemiluminescence

## 2

### **Description**

Fasting blood sugar

### **Timepoint**

At baseline and one month later

### **Method of measurement**

chromatography

## 3

### **Description**

Lipid Profile

### **Timepoint**

At baseline and one month later

### **Method of measurement**

chromatography

## **Intervention groups**

### 1

#### **Description**

Intervention group: Ginger capsule 500 mg 2 times a day

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Placebo

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Mofatteh Clinic

##### **Full name of responsible person**

Hamide Ashraf

##### **Street address**

10 Golestan Ave; Imam Khomeini Blvd; Shahid Mofteh Clinic

##### **City**

Yasuj

##### **Province**

Kohgilouyeh-va-Boyerahmad

##### **Postal code**

7591741417

##### **Phone**

+98 74 3322 3299

##### **Email**

tbsonati94@yahoo.com

##### **Web page address**

<http://www.cmofateh.yums.ac.ir/>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Dr. Younes Qasemi

##### **Street address**

Zand Street, Next to the Red Crescent, Central Building of Shiraz University of Medical Sciences, Seventh Floor

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

71345-1978

##### **Phone**

+98 71 3235 7282

##### **Fax**

+98 71 3212 2430

##### **Email**

[vcrdep@sums.ac.ir](mailto:vcrdep@sums.ac.ir)

##### **Web page address**

<http://research.sums.ac.ir/>

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Hamide Ashraf

##### **Position**

resident

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Traditional Medicine

##### **Street address**

No. 3, Tohid Ave ; Bagherkhan Blvd

##### **City**

Yasuj

**Province**

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**Postal code**

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**Phone**

0098 74 3233667

**Email**

tbsonati94@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Hamide Ashraf

**Position**

resident

**Latest degree**

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Shiraz University of Medical Sciences

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Hamide Ashraf

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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**

Undecided - It is not yet known if there will be 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