

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

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

Kohgilouyeh-va-Boyrahmad

Postal code

7591984989

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

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Person responsible for updating data

Contact

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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