

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### The Efficacy of Oral Consumption of Nigella Sativa with Placebo on Serum TSH in Patients with Hypothyroidism treated with Levothyroxine

#### Protocol summary

##### Study aim

Determine the effect of Nigella sativa on hypothyroidism

##### Design

A randomized, Triple-blind, clinical trial study with a two parallel groups of 21 patients with hypothyroidism in placebo and drug for 2 months

##### Settings and conduct

42 patients with hypothyroidism who admitted to the Endocrine Clinic at Imam Khomeini Hospital in Tehran were selected according to inclusion criteria and randomly divided into two parallel groups of receiving Nigella sativa and placebo for 2 month. According to the computer based randomization table, medications (placebo and nigella sativa) will be given by patients with a specific Cod. Patients, researcher and analyzers are unaware of the type of medication

##### Participants/Inclusion and exclusion criteria

1. Hypothyroid patients who are diagnosed with endocrinologist and treated with levothyroxine for at least 2 consecutive visits with  $10 > TSH > 2$ ; 2. Age between 16 and 65 years; 3. Patient's written consent form prior to participation in the study; 4. No history of heart disease, coagulation disorders, autoimmune disorders,; pituitary and hypothalamic problems and kidney and malignant diseases,; other thyroid disorders including Graves; 5. No pregnancy or lactation;

##### Intervention groups

42 hypothyroid patients under treatment were divided into 2 groups, including (1) drug group (2g/day of Nigella sativa powder equivalent to four capsules 250 mg) and (2) placebo (four 250 mg capsules containing starch powder) group for 2 months with levothyroxine drug.

##### Main outcome variables

serum concentration of Thyroid stimulating hormone

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20171113037424N2**

Registration date: **2019-03-05, 1397/12/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-05, 1397/12/14**

Update count: **0**

#### Registration date

2019-03-05, 1397/12/14

#### Registrant information

##### Name

Maryam Fatemi tekie

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5121 5080

##### Email address

dr.fatemi78@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-03-21, 1397/01/01

#### Expected recruitment end date

2019-03-21, 1398/01/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Efficacy of Oral Consumption of Nigella Sativa with Placebo on Serum TSH in Patients with Hypothyroidism treated with Levothyroxine

**Public title**

Effect of Nigella Sativa in Hypothyroidism

**Purpose**

Treatment

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

Hypothyroid patients who are diagnosed with endocrinologist and treated with levothyroxine for at least 2 consecutive visits with  $10 > TSH > 2$  age between 16 and 65 years Patient's written consent form prior to participation in the study No history of heart disease, coagulation disorders, autoimmune disorders, pituitary and hypothalamic problems and kidney and malignant diseases, and other thyroid disorders such as Graves No Pregnancy or lactation

**Exclusion criteria:**

Taking any herbal drug that interferes with Nigella sativa

**Age**

From **16 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization of control and intervention groups. Participants will be divided into the control and intervention group using a simple randomization model (computer randomization method) and also according to the random number table.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

42 patients with hypothyroidism and undergoing treatment will be selected based on inclusion criteria. According to the computer based randomization table, medications (placebo and nigella sativa) will be given by patients with a specific Cod. Patients, researcher and analyzers are unaware of the type of medication.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of shahed university of medical sciences

**Street address**

No5, Golkar Alley, Wahhag Alley, Mahmoodi street, Shahidmadani Ave, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1641616741

**Approval date**

2018-03-18, 1396/12/27

**Ethics committee reference number**

IR.Shahed.REC.1396.125

**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**

Thyroid-Stimulating Hormone (TSH)

**Timepoint**

Before experiment and 2 months after experiment

**Method of measurement**

Laboratory\_Thyroid-Stimulating Hormone(RIA assesment )

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

Thyroid Questionnaire Score

**Timepoint**

before experiment and after 2month

**Method of measurement**

Zulewski's clinical score for hypothyroidism

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

Intervention group: 2g/day of Nigella sativa powder equivalent to four capsules 250 mg and twice a day for 2 months plus levothyroxine tablets

**Category**

Treatment - Drugs

**2****Description**

Control group: .placebo group (four 250 mg capsules containing starch powder and twice a day) for 2 months with levothyroxine drug.

**Category**

Placebo

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

Imam Khomeini Hospital Endocrinology Clinic

**Full name of responsible person**

Elham Emaratkar

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Imam Khomeini Hospital, Keshavarz Boulevard,

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

Shahed University

**Full name of responsible person**

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Shahed University, opposite the shrine of Imam Khomeini, Persian Gulf Highway Tehran Qom, Tehran,

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

Yes

**Title of funding source**

Shahed University

**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**

Shahed University

**Full name of responsible person**

Maryam Fatemi Tekieh

**Position**

Resident of Traditional Medicine, School of Medicine, Shahed University

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

assistant professor of traditional medicine

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahed University  
**Full name of responsible person**  
Maryam Fatemi Tekieh  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
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**Province**

## 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