

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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)

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Email address

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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 $10 > \text{TSH} > 2$ 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

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

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

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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

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Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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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