Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 ofThyroid 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

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Iran (Islamic Republic of)

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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> TSH>2 age beween 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
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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
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1

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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
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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