Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

The effect of hydroalcoholic extract of Illicium verum on serum levels of thyroid hormones and stress oxidative index in patients with hypothyroidism: a double-blind randomized clinical trial

Protocol summary

Study aim

Determination of Illicium verum supplement effect on serum levels of thyroid hormones and oxidative stress status in patients with hypothyroidism

Design

In this clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3, forty-four patients with hypothyroidism who meet the inclusion criteria and referred to the specialized clinic of Qazvin University of Medical Sciences, are selected. Participants are randomly divided into intervention and control groups using random blocks and a code is assigned to each participant.

Settings and conduct

The aim of this study is to determine the effectiveness of the hydroalcoholic extract of Illicium verum supplement as a randomized double-blind clinical trial on patients with hypothyroidism referred to the specialized department of Qazvin University of Medical Sciences. The subjects in the intervention and control groups will receive Illicium verum supplements or a placebo for 2 months. At the beginning and end of the study, 10 ml of blood samples were taken from the participants in the fasting state. In this study, participants and the researcher will be blind to being placed in groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the patients who are 20-50 years old diagnosed with hypothyroidism; BMI less than 30, Signed informed consent by the patient. Exclusion criteria: Pregnancy; lactation; menopause; infectious disease; inflammatory disease; diabetes and cancer; taking antioxidant supplements over the past three months; drug use over the past three months including diabetes, glucocorticoids, lipid-lowering, and weight-loss drugs

Intervention groups

Intervention group: the group receiving an alcoholic extract of Illicium verum (1500 mg daily). Control group: the group receiving placebo.

Main outcome variables

Thyroid hormones include thyroxine, triiodothyronine, and thyroid-stimulating hormone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141025019669N19**
Registration date: **2021-09-24, 1400/07/02**
Registration timing: **prospective**

Last update: **2021-11-14, 1400/08/23**
Update count: **1**

Registration date

2021-09-24, 1400/07/02

Registrant information

Name

Hossein Khadem Haghighian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 28 3375 2135

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2021-10-27, 1400/08/05

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of hydroalcoholic extract of Illicium verum on serum levels of thyroid hormones and stress oxidative index in patients with hypothyroidism: a double-blind randomized clinical trial

Public title
Illicium verum supplementation in patients with hypothyroidism
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with hypothyroidism Patient 20-50 years old Having a body mass index less than 30 Consent signed by the patient
Exclusion criteria:
Pregnancy and lactation Infectious diseases, Inflammatory diseases, Diabetes, Cancer Taking antioxidant supplements in the last three months Drug use over the past three months, including diabetes, glucocorticoids, lipid-lowering drugs, and weight-loss drugs
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
It will be done randomly using the lottery method. Each patient will receive a number or code, and then we will write the numbers on pieces of paper. We will then place the pieces of paper in a container and select the samples according to the sample size.
Blinding (investigator's opinion)
Double blinded
Blinding description
Supplements and placebo will be placed in similar containers and encode by someone except the investigator, so patients and the investigator will be blinded to medicine and placebo groups.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University Of Medical Sciences
Street address
Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin
City
Qazvin
Province
Qazvin
Postal code
34197-59811
Approval date
2021-09-07, 1400/06/16
Ethics committee reference number
IR.QUMS.REC.1400.249

Health conditions studied

1

Description of health condition studied
Hypothyroidism
ICD-10 code
E03
ICD-10 code description
Other hypothyroidism

Primary outcomes

1

Description
Thyroxine hormone
Timepoint
Before the intervention and after the intervention
Method of measurement
ELISA

2

Description
Triiodothyronine hormone
Timepoint
Before the intervention and after the intervention
Method of measurement
ELISA

3

Description

Thyroid-stimulating hormone

Timepoint

Before the intervention and after the intervention

Method of measurement

ELISA

4

Description

Total antioxidant capacity

Timepoint

Before the intervention and after the intervention

Method of measurement

ELISA

5

Description

Malondialdehyde

Timepoint

Before the intervention and after the intervention

Method of measurement

ELISA

6

Description

Depression Anxiety and Stress

Timepoint

Before the intervention and after the intervention

Method of measurement

Depression Anxiety and Stress Scale (DASS-21)

Secondary outcomes

1

Description

Body mass index

Timepoint

Before the intervention and after the intervention

Method of measurement

Using the formula (weight in kilograms divided by height in meters squared)

Intervention groups

1

Description

Intervention group: Hydroalcoholic extract of Illicium verum, Three 500 mg capsules per day for two months

Category

Treatment - Drugs

2

Description

Control group: Three placebo capsules containing wheat flour daily for two months

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Hossein Khadem Haghighian

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Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Seyyed Mehdi Mirhashemi

Street address

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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

Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Hossein Khadem Haghighian
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data after people are unrecognizable
When the data will become available and for how long
After completing the study and publishing the article
To whom data/document is available
All researchers
Under which criteria data/document could be used
There is nothing wrong with using the data as long as the source of the data is mentioned.
From where data/document is obtainable
By contacting the email address of a person responsible for general inquiries khademnut@yahoo.com
What processes are involved for a request to access data/document
After consulting with the research team, the data will be provided to the applicant, which will probably be a one-month process.
Comments