

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparing the effect of aqueous extract of *Illicium verum* and placebo on serum levels of thyroid hormones in patients with hypothyroidism: a double-blind randomized clinical trial (Pilot study)

Protocol summary

Study aim

Determination of *Illicium verum* supplement effect on serum levels of thyroid hormones in patients with hypothyroidism

Design

In this clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3, twenty 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 evaluate the aqueous extract of *Illicium verum* supplement as a randomized, double-blind clinical trial on patients with hypothyroidism referring to the specialized department of the Velayat hospital of Qazvin University of Medical Sciences.

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. Non-inclusion 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 aqueous extract of *Illicium verum* (1500 mg daily). Control group: the group receiving placebo.

Main outcome variables

Thyroid hormones include thyroxine, triiodothyronine, thyroid-stimulating hormone and the extent of depression, anxiety, and stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141025019669N18**

Registration date: **2021-04-12, 1400/01/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-23, 1400/08/01**

Update count: **1**

Registration date

2021-04-12, 1400/01/23

Registrant information

Name

Hossein Khadem Haghighian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3375 2135

Email address

khadem.h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-05-10, 1400/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparing the effect of aqueous extract of <i>Illicium verum</i> and placebo on serum levels of thyroid hormones in patients with hypothyroidism: a double-blind randomized clinical trial (Pilot study)
Public title	<i>Illicium verum</i> supplementation in patients with hypothyroidism
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Patients with hypothyroidism Patient 50-20 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 - Investigator
Sample size	Target sample size: 20
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	
<u>1</u>	
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	2021-03-03, 1399/12/13
Ethics committee reference number	IR.QUMS.REC.1399.521
Health conditions studied	
<u>1</u>	
Description of health condition studied	Hypothyroidism
ICD-10 code	E03
ICD-10 code description	Other hypothyroidism
Primary outcomes	
<u>1</u>	
Description	Thyroxine hormone
Timepoint	Before the intervention and after the intervention
Method of measurement	ELISA
<u>2</u>	
Description	Triiodothyronine hormone
Timepoint	Before the intervention and after the intervention
Method of measurement	ELISA
<u>3</u>	
Description	Thyroid-stimulating hormone
Timepoint	Before the intervention and after the intervention
Method of measurement	ELISA

4

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

Intervention groups

1

Description

Intervention group: Aqueous 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 - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Hossein Khadem Haghighian

Street address

Qazvin University of Medical Science, Shahid Bahonar
Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mahdi Emamjomeh

Street address

Qazvin University of Medical Science, Shahid Bahonar
Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

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

Iran 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

Street address

Qazvin University of Medical Science, Shahid Bahonar
Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

Person responsible for scientific 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

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

59811 -34197

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

Person responsible for updating data

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

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

59811 -34197

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

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