Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

compare the effect of Nigella Sativa powder in the supplement group and placebo on the Serum Levels of Thyroid Hormones, Beta Transforming Growth Factor, Interlukin 23, Lipid Pattern and markers of oxidative stress in Hashimoto’s Thyroiditis patients

Protocol summary

Summary

The aim of this randomized, placebo-controlled trial is to investigate the effects of Nigella sativa powder on serum Levels of Thyroid Hormones, Beta Transforming Growth Factor, Interleukin 23, lipid profile and markers of oxidative stress in Hashimoto’s Thyroiditis patients. Forty Hashimoto’s Thyroiditis patients that their disease was confirmed by pathological assessment will be enrolled in this study according inclusion and exclusion criteria. The participants will be assigned into control and treatment groups using permuted-blocks randomization and will be studied in Double-Blind way. Treatment group will receive 2 gram of Nigella sativa powder daily and Placebo Group will receive 2 gram of starch daily along with their lunch and dinner meals for 8 weeks. demographic information, Physical Activity, and 24-hour recall Questionnaire will be completed before and 2 month after the intervention. Blood Samples (7CC) will be taken before and after the intervention and will be kept under -70 Celsius for the relevant tests.Related biochemical measurements will be done by Elisa Kits.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090819082N2**
Registration date: **2014-09-29, 1393/07/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-09-29, 1393/07/07

Registrant information

Name

Mahdieh Abbasalizad Farhangi

Name of organization / entity

Department of Community Nutrition School of Nutrition

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

compare the effect of Nigella Sativa powder in the supplement group and placebo on the Serum Levels of Thyroid Hormones, Beta Transforming Growth Factor, Interlukin 23, Lipid Pattern and markers of oxidative stress in Hashimoto’s Thyroiditis patients

Public title

The Effect of oral consumption of Nigella Sativa in the

treatment of autoimmune Hypothyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age Range of 20-50; Suffering from Hashimoto disease with the Diagnosis of Physician based on specialized Tests; Completing Informed Consent Form. Exclusion Criteria: not signed informed consent Form; physiologic Special conditions such as pregnancy and breast-feeding; receiving supplements such as Vitamin E, C, Zinc, Folat, Cobalamin, Soy fitoestrogens in the last 3 month; suffering from any auotoimmune disease; history of thyroid operation, following any special diet

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Golbad Street, Tabriz, East Azerbayjan, Iran

City

Tabriz

Postal code

Approval date

2014-08-04, 1393/05/13

Ethics committee reference number

9369

Health conditions studied

1

Description of health condition studied

Hashimoto’s Thyroiditis

ICD-10 code

E06.3

ICD-10 code description

Autoimmune thyroiditis

Primary outcomes

1

Description

Serum concentration ofIL-23

Timepoint

At baseline and after 2 months of intervention

Method of measurement

ELISA

2

Description

Serum concentration ofTGF-β

Timepoint

At baseline and after 2 months of intervention

Method of measurement

ELISA

3

Description

Serum concentration ofT4, T3، TSH،TPOAb

Timepoint

At baseline and after 2 months of intervention

Method of measurement

ELISA

4

Description

Serum concentration ofT4, T3، TSH،TPOAb

Timepoint

At baseline and after 2 months of intervention

Method of measurement

ELISA

5

Description

Added at 2017-02-12: Serum Concentrations of MDA, GPX, SOD and TAC

Timepoint

Added at 2017-02-12: Before and after intervention

Method of measurement

Added at 2017-02-12: ELIZA

6

Description

Added at 2017-02-12: Serum TAC

Timepoint

Added at 2017-02-12: At baseline and after 2 months of

intervention

Method of measurement

Added at 2017-02-12: ELIZA

7

Description

Added at 2017-02-12: Serum CAT

Timepoint

Added at 2017-02-12: At baseline and after 2 months of intervention

Method of measurement

Added at 2017-02-12: ELIZA

8

Description

Added at 2017-02-12: Serum GPX

Timepoint

Added at 2017-02-12: At baseline and after 2 months of intervention

Method of measurement

Added at 2017-02-12: ELIZA

9

Description

Added at 2017-02-12: Serum SOD

Timepoint

Added at 2017-02-12: At baseline and after 2 months of intervention

Method of measurement

Added at 2017-02-12: ELISA

Secondary outcomes

1

Description

Physical Activity

Timepoint

At baseline and after 2 months of intervention

Method of measurement

Physical Activity Questionare

2

Description

Receiving Energy and Macronutrients

Timepoint

Before The first month termination and after the eight week

Method of measurement

24-hour memorial questionare

3

Description

BMI

Timepoint

At baseline and after 2 months of intervention

Method of measurement

Weight divided by Height Square

Intervention groups

1

Description

Nigella sativa group will receive 2 gram of Nigella sativa powder in the form of 1 gram packs with lunch and dinner meals for 8 weeks.The supplement will be given weekly and during the consumption possible side effects and keeping on consumption will be monitored

Category

Treatment - Drugs

2

Description

Placebo group will receive 2 gram of starch in the form of 1-gram packs with lunch and dinner meals weekly for 8 weeks and during the consumption possible side effects and keeping on consumption will be monitored

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Sedieghe Tahereh Endocrinology and Metabolism Research Centre

Full name of responsible person

Dr. Mansoor Siavashi

Street address

Esfahant Sedieghe Tahereh Endocrinology and Metabolism Research Centre, Khorram St. Isfahan

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Golbad Street, Tabriz, East Azerbayjan

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for Research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Fax
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty