Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

The effect of supplementation with Nigella Sativa on serum Nesfatin-1, vascular endothelial growth factor (VEGF) and insulin resistance in patients with Hashimoto in comparison of placebo treated group

Protocol summary

Summary
In the current randomized double blind placebo controlled trial, 40 patients with hashimoto thyroiditis are enrolled. Patients are divided into two intervention and placebo groups with random permuted block and are matched according to age, gender and drug dosage. After signing written informed consent anthropometric parameters including weight, height and BMI will be measured and subjects in intervention and control group will receive 1 gram/day packages of Nigella Sativa or placebo for four weeks. The study's inclusion criteria are as follows: aged between 20-50 years old, diagnosis of Hashimoto thyroiditis by physician, completing written informed consent. Exclusion criteria are: pregnancy, lactation, taking supplements such as vitamin E, C, zinc, folate, cobalamin and phytoestrogens in past three months, any history of celiac, cardiovascular disease, arthritis, autoimmune and inflammatory disease, thyroid abnormalities and surgeries, and being on any special diets.

General information

Acronym
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IRCT registration information
IRCT registration number: **IRCT2015021719082N4**
Registration date: **2015-03-15, 1393/12/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2015-03-15, 1393/12/24

Registrant information

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Recruitment status
Recruitment complete

Funding source
Tabriz University of Medical Sciences

Expected recruitment start date
2014-12-27, 1393/10/06
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
The effect of supplementation with Nigella Sativa on serum Nesfatin-1, vascular endothelial growth factor (VEGF) and insulin resistance in patients with Hashimoto in comparison of placebo treated group

Public title
The effect of Nigella Sativa on treatment of Hashimoto thyroiditis
Purpose
Treatment
Inclusion/Exclusion criteria
(Inclusion criteria: aged between 20-50 years old;

physician diagnosis of hashimoto thyroiditis; completeing written informed consent) (Exclusion criteria: pregnancy, lactation, taking supplements such as vitamin E, C, zinc, folate, cobalamin and phytoesterogens in past three months;any history of celiac, cardiovascular disease, arthritis, autoimmune and inflammatory disease; thyroid abnormalities and surgeries and being on diet)

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

Gender
Both

Phase
N/A

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
Research Undersecretary of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences

City
Tabriz

Postal code
516614711

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
93173

Health conditions studied

1

Description of health condition studied
Hashimoto Thyroiditis

ICD-10 code
E06.3

ICD-10 code description
Autoimmune Thyroiditis

Primary outcomes

1

Description
Nesfatin-1

Timepoint
before and 4 weeks after intervention

Method of measurement
ELIZA method

2

Description
Vascular Endotheilal Growth Factor (VEGF)

Timepoint
Before and 4 weeks After Intervention

Method of measurement
ELIZA method

Secondary outcomes

1

Description
Fasting Blood Sugar

Timepoint
Before and Four Weeks After Intervention

Method of measurement
Enzymatic Method

2

Description
Insulin Resistance

Timepoint
Before and Four Weeks After Intervention

Method of measurement
HOMA-IR

Intervention groups

1

Description
Placebo: 1 gram per day starch as placebo for four weeks treatment period

Category
Treatment - Drugs

2

Description
Supplement: one gram per day Nigella Sativa for four weeks treatment period

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Nutrition Research Center

Full name of responsible person
Dr Mahdieh Abbasalizad Farhangi

Street address
Department of Community Nutrition, Faculty of Nutrition, Tabriz University of Medical Sciences

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Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Undersecretary of Tabriz University of Medical Sciences

Full name of responsible person
Dr Mohammad-Reza Rashidi

Street address
Tabriz University of Medical Sciences

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Research Undersecretary of 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

Contact

Name of organization / entity
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Assistant Professor (Ph.D.)

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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