

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Oct 2021

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

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

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; completing written informed consent) (Exclusion criteria: 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 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 Endothelial 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

City

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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Full name of responsible person

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Position

Assistant Professor (Ph.D.)

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Position

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+98 41 3335 7580

Fax**Email****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