

# 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)

##### Phone

+98 413357580

##### Email address

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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**

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

**Full name of responsible person**

Dr Mahdieh Abbasalizad Farhangi

**Position**

Assistant Professor (Ph.D.)

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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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*