

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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)

##### Phone

+98 413357580

##### Email address

abbasalizadm@tbzmed.ac.ir

#### 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, Folate, Cobalamin, Soy phytoestrogens in the last 3 months; suffering from any autoimmune 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 Azerbaijan, 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 of fL-23

#### Timepoint

At baseline and after 2 months of intervention

#### Method of measurement

ELISA

### 2

#### Description

Serum concentration of TGF- $\beta$

#### Timepoint

At baseline and after 2 months of intervention

#### Method of measurement

ELISA

### 3

#### Description

Serum concentration of T4, T3, TSH, TPOAb

#### Timepoint

At baseline and after 2 months of intervention

#### Method of measurement

ELISA

### 4

#### Description

Serum concentration of T4, 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: ELISA

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#### 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 questionnaire

### **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 Azerbaijan

##### **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*

**City**

Tabriz

**Postal code****Phone**

+98 41 1335 7580

**Fax****Email**

abbasalizadm@tbzmed.ac.ir

**Web page address****Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Sirus Tajmiri

**Position**

MSc student in health sciences in nutrition

**Other areas of specialty/work****Street address**

Attar Neishabouri Street, Golgasht Street, Tabriz, East Azerbaijan, Islamic Republic Of Iran

**City**

Tabriz

**Postal code****Phone**

+98 910 515 0752

**Fax****Email****Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Siros Tajmiri

**Position**

MSc student in health sciences in nutrition

**Other areas of specialty/work****Street address**

Attar St., Golgasht St., Tabriz, East Azerbaijan

**City**

Tabriz

**Postal code****Phone****Fax****Email****Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mehديه Abbasalizadeh Farhangi

**Position**

Assistant professor

**Other areas of specialty/work****Street address**

Attar Neishabouri Street, Golgasht Street, Tabriz, East Azerbaijan

**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*