

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Effect of Bread With Nigella Sativa on Lipid Profiles, Apolipoproteins, Inflammatory Factors and Coagulatory Factors in Metabolic Syndrome Patients

#### Protocol summary

##### Summary

Main goal : Survey of effect of bread with Nigella sativa on Lipid Profiles, Apolipoproteins, Inflammatory Factors and Coagulatory Factors in Metabolic Syndrome patients. Inclusion criteria :Having at least 3 items of 5 items of Metabolic Syndrome. Exclusion criteria : Change in medical therapy,Pregnancy and Having chronic diseases . Study population :persons(Male and Female) With Metabolic Syndrome in age range 20-65 years old Sample size : 48 persons Study intervention :Effects of bread with Nigella sativa on blood and clinical parameters Type of study :The Participants enter in a cross over study as in phase 1, half of those (intervention group)consume dietetic bread with nigella sativa and the others(control group) consume regular dietetic bread daily for 2 months and after a washout period (15 days),groups position is exchanged and phase 2 continue for 2 month. Time period :July - December 2015 Primary outcomes : Change in blood parameters

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2015041821815N1**

Registration date: **2015-06-30, 1394/04/09**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-06-30, 1394/04/09

##### Registrant information

###### Name

Alireza Mohtashami

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 2752

##### Email address

mohtashami\_52@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2015-07-23, 1394/05/01

##### Expected recruitment end date

2015-09-21, 1394/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Bread With Nigella Sativa on Lipid Profiles, Apolipoproteins, Inflammatory Factors and Coagulatory Factors in Metabolic Syndrome Patients

##### Public title

Effect of Bread With Nigella Sativa on Blood Factors in Metabolic Syndrome Patients

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion Criteria :Having 3 Items of 5 Items of Metabolic Syndrome :Waist Circumference over 102 for Men and over 88 Centimeter for Women, Serum Triglycerid 150 mg/dl or More or Using of Drug , Serum HDL under 40 for

Men and under 50 for Women, Fasting Blood Sugar 100 mg/dl or More or Using of Drug , Blood Pressure 130/85 or More or Using of drug. Exclusion Criteria :Change in Type or Dosage of Drug or Supplements in Medical Therapy,Pregnancy,Having Chronic Diseases in Liver, kidney, Neural and muscular system.

#### Age

From **20 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **48**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Crossover

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Isfahan University of Medical Sciences

###### Street address

Isfahan University of Medical Sciences, Hezargarib Street

###### City

Isfahan

###### Postal code

8174673461

##### Approval date

2014-11-16, 1393/08/25

##### Ethics committee reference number

393636

### Health conditions studied

#### 1

##### Description of health condition studied

Metabolic Syndrome

##### ICD-10 code

-

##### ICD-10 code description

-

#### 2

##### Description of health condition studied

Obesity

##### ICD-10 code

E66

##### ICD-10 code description

Obesity

### Primary outcomes

#### 1

##### Description

Blood Parameters

##### Timepoint

Before and After Intervention ( as Crossover Design )

##### Method of measurement

Evaluation of Blood Parameters with Lab Technics

### Secondary outcomes

#### 1

##### Description

Medical and Body Parameters (Blood Pressure, Weight, Waist Circumference)

##### Timepoint

Before and After Intervention (as Crossover Design)

##### Method of measurement

Measuring of Blood Pressure with Sphygmomanometer, Measuring of Waist Circumference with Meter, Measuring of Weight with Balance Dvice

### Intervention groups

#### 1

##### Description

It is prepared for intervention group to use a 100 grams dietetic bread with nigella sativa(3 grams) and having a balanced diet with decreasing 10 percent in dietary energy for 2 months.

##### Category

Lifestyle

#### 2

##### Description

It is prepared for control group to use a 100 grams dietetic bread and having a balanced diet with decreasing 10 percent in dietary energy for 2 months.

##### Category

Lifestyle

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Faculty of Medical Sciences, Azad University of Chalus

**Full name of responsible person**

Alireza Mohtashami

**Street address**

Azad University of Chalus, Hefdaheshahrivar Street,  
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**Email**

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**Web page address**

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr.Mahdi Nematbakhsh

**Street address**

Isfahan University of Medical Sciences, Hezargarib  
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**City**

Isfahan

**Grant name**

اجرای برنامه های آموزشی

**Grant code / Reference number**

10506

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

Yes

**Title of funding source**

Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Alireza Mohtashami

**Position**

Ph.D Candidate in Nutrition Sciences

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

Isfahan University of Medical Sciences, Hezargarib  
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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Mohammadhasan Entezari

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## Person responsible for updating data

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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*