

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 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

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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 Device

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

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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

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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**

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Full name of responsible person

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Position

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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