Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Oct 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 paitents. 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 Presure 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 musclelar 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 Divice

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, Chalus
City
Chalus

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 Street
City
Isfahan
Grant name
اجرای برنامه های اموزشی
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 Street
City
Isfahan
Postal code
8174673461
Phone
+98 31 3792 2752
Fax
+98 31 3668 2509
Email
mohtashami_52@yahoo.com
Web page address
www.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Mohammadhasan Entezari
Position
Ph.D
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences, Hezargarib Street
City
Isfahan
Postal code
8174673461
Phone
+98 31 3792 2775
Fax
+98 31 3668 2509
Email
entezari@hlth.mui.ac.ir
Web page address
WWW.mui.ac.ir

Person responsible for updating data

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 Street
City
Isfahan
Postal code
8174673461
Phone
+98 31 3792 2752
Fax
+98 31 3668 2509
Email
mohtashami_52@yahoo.com
Web page address
www.mui.ac.ir

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