Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Oct 2026

Effects of concomitant administration of flaxseed and hesperidin on cardiac and metabolic parameters in patients with prediabetes

Protocol summary

Study aim

The aim of this study was to determine the effects of concomitant administration of flaxseed and hesperidin on cardiac and metabolic parameters in patients with prediabetes.

Design

This study was an open-label, randomized controlled clinical trial with two parallel groups. 48 patients were randomly assigned to the intervention and control group.

Settings and conduct

Patients with prediabetes referring to the university outpatient Nutrition Clinic were invited to participate in this research, and the research goals and methods were explained for them. After assessing the entrance criteria and obtaining written consent, 10 cc blood samples are taken. The food recall questionnaire is completed. Supplements are given to patients for a month.

Participants/Inclusion and exclusion criteria

Patients with prediabetes who were not on a diet or medication therapy to lower their blood pressure, blood sugar and lipid profile were enrolled.

Intervention groups

Subjects were randomly assigned to receive lifestyle intervention plus combination therapy of brown flaxseed (30 g milled) and hesperidin (two 500 mg capsules) (intervention group) or lifestyle modification alone (control group) for 12 weeks.

Main outcome variables

Weight; Waist Circumference; Blood Pressure; Serum concentration of fasting blood sugar; insulin; triglyceride; high-density lipoprotein cholesterol; low-density lipoprotein cholesterol; high sensitive C reactive protein; tumor necrosis factor-alpha

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181120041710N2**
Registration date: **2020-02-10, 1398/11/21**
Registration timing: **retrospective**

Last update: **2020-02-10, 1398/11/21**
Update count: **0**

Registration date

2020-02-10, 1398/11/21

Registrant information

Name

Zahra Yari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2235 7484

Email address

zahrayari_nut@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-01, 1396/10/11

Expected recruitment end date

2018-10-01, 1397/07/09

Actual recruitment start date

2018-01-01, 1396/10/11

Actual recruitment end date

2018-10-01, 1397/07/09

Trial completion date

2018-10-01, 1397/07/09

Scientific title

Effects of concomitant administration of flaxseed and hesperidin on cardiac and metabolic parameters in patients with prediabetes

Public title

Effects of flaxseed and hesperidin in patients with prediabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 18 to 70 years Diagnosed with prediabetes Having body mass index (BMI) range of 25 to 40 kg/m2

Exclusion criteria:

History of cardiovascular, pulmonary, renal, hepatic and gastrointestinal disease Taking anti-hypertensive, glucose-lowering medications, lipid-modifying agents and omega-3 dietary supplement Being under treatment with steroids and nonsteroidal anti-inflammatory drugs Being on a calorie-restricted regimen within 3 months before the commencement of the trial Being pregnant or lactating

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **48**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation method is simple randomization using a random number table. The unit of allocation is the individual.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Vice Chancellor of Research, Shahid Beheshti University of Medical Sciences

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2019-12-29, 1398/10/08

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.561

Health conditions studied

1

Description of health condition studied

prediabetes

ICD-10 code

R73.01

ICD-10 code description

Impaired fasting glucose

Primary outcomes

1

Description

Weight

Timepoint

Baseline and Week 12

Method of measurement

Scale

2

Description

Waist circumference

Timepoint

Baseline and Week 12

Method of measurement

Meter

3

Description

Blood pressure

Timepoint

Baseline and Week 12

Method of measurement

Mercury Sphygmomanometer

4

Description

Serum concentration of fasting blood sugar

Timepoint

Baseline and Week 12

Method of measurement

Enzymatic method

5

Description

Serum concentration of fasting blood insulin

Timepoint

Baseline and Week 12
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

6

Description
Serum concentration of triglyceride
Timepoint
Baseline and Week 12
Method of measurement
Enzymatic method

7

Description
Serum concentration of HDL
Timepoint
Baseline and Week 12
Method of measurement
Enzymatic method

8

Description
Serum concentration of LDL
Timepoint
Baseline and Week 12
Method of measurement
Enzymatic method

9

Description
Serum concentration of hs-CRP
Timepoint
Baseline and Week 12
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

10

Description
Serum concentration of TNF-alpha
Timepoint
Baseline and Week 12
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: lifestyle modification plus combination therapy of brown flaxseed (30 g milled) and hesperidin (two 500 mg capsules). Also, patients were instructed to divide supplements into two equal doses (one capsule of hesperidin and 15 g milled flaxseed), one with breakfast and the other at lunchtime.
Category
Treatment - Other

2

Description
Control group: lifestyle modification
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
University outpatient Nutrition Clinic
Full name of responsible person
Zahra Yari
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Student Research Committee, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Amir Mohammad Mortazavian
Street address
Block 2, Shahid Beheshti University of Medical Sciences, Evin Ave.
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Postal code
1985717443
Phone
+98 21 23871
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Student Research Committee, Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Yari
Position
Ph.D student
Latest degree
Master
Other areas of specialty/work
Nutrition
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available