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)
Phone
+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

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

info@nnftri.ac.ir

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.

City

Tehran

Province

Tehran

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
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7483
Email
zahrayari_nut@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Yari
Position
Ph.D candidate
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
No. 7, Hafezi (Arghavan) St., Farahzadi Ave., Shahrake Ghods(Gharb) town, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7484
Fax
Email
zahrayari_nut@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Yari
Position
Ph.D student
Latest degree
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Nutrition
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7483
Email
zahrayari_nut@yahoo.com

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