

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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/m<sup>2</sup>

### 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

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**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**

Master

**Other areas of specialty/work**

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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