

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of date seed powder on glycemic markers and lipid profile in overweight or obese women

Protocol summary

Study aim

Effect of date seed powder on glycemic markers and blood lipid profile in overweight or obese women

Design

A randomized, double-blind, placebo-controlled clinical trial. Study population: 124 overweight or obese women referred to the nutrition clinic into 2 groups receiving date seed powder supplement (400 mg per day) and control group receiving placebo (receiving 400 mg lactose-free powdered milk per day). At first people will fill in Informed consent form, demographic and physical activity questioners and then randomly assigned to either the intervention group and control. Both groups will receive 2 capsules daily after meals for 90 days. Height, weight, waist circumference and hip circumference will be measured at the beginning and end of the study. To measure glucose, HbA1C, insulin and the pattern of lipids and lipoproteins, 5 ml of blood will be taken before the intervention and at the end of the 90-day period. Systolic and diastolic blood pressure will be measured at the beginning and end of the study in all individuals. Used to randomize random sequence generation in excel software.

Settings and conduct

Women referring to nutrition and diet therapy clinic in Shiraz

Participants/Inclusion and exclusion criteria

Overweight or obese 20-50-year-old women with a body mass index of 25 to 40 who tend to cooperate.

Intervention groups

The intervention group received 400 mg of date seed powder (2 capsules of 200 mg) daily and the placebo group received 2 capsules daily (each capsule containing 200 mg of lactose-free milk powder). The intervention lasts for 90 days.

Main outcome variables

Lipid profile, fasting blood sugar, HbA1C, anthropometric variables and blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211217053429N1**

Registration date: **2022-01-08, 1400/10/18**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-08, 1400/10/18**

Update count: **0**

Registration date

2022-01-08, 1400/10/18

Registrant information

Name

Maral Hashemzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3232 6788

Email address

mary.hashemzadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-04-19, 1401/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of date seed powder on glycemic markers and lipid profile in overweight or obese women

Public title

Effect of date seed powder on blood sugar and blood lipid Index.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to cooperate 20-50 years old women Body mass index 25 to 40

Exclusion criteria:

Pregnancy and lactation Taking lipid and blood sugar drugs Taking Weight loss supplements and special diet Menopause Diabetes Hypo or hyperthyroidism Anemia Gastrointestinal problems

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

The researcher selects the individuals who meet the inclusion criteria and registers their names in a list by number, and then divides the participants into intervention and placebo groups using random allocation. Random Sequence generation will be randomly assigned by a table of random numbers in Exel software.

Blinding (investigator's opinion)

Double blinded

Blinding description

All participants in the project assume that they have received the intervention and are unaware that they are in the date seed powder group or the placebo group. Also, the clinical researcher and data analyst is unaware of which group the participants belong to (date seed powder recipient or placebo recipient).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Nutrition Faculty of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences, Zand St, Shiraz.

City

Shiraz

Province

Fars

Postal code

713451978

Approval date

2021-11-14, 1400/08/23

Ethics committee reference number

IR.SUMS.SCHEANUT.REC.1400.060

Health conditions studied

1

Description of health condition studied

obesity and lipid disorders

ICD-10 code

E65-E68

ICD-10 code description

Obesity and other hyperalimentation

Primary outcomes

1

Description

Metabolic parameters

Timepoint

Before and three months after intervention

Method of measurement

Standard laboratory kits

2

Description

Anthropometric indices

Timepoint

Before and three months after intervention

Method of measurement

Digital scales and standard meters

3

Description

Measurement of blood pressure

Timepoint

Before and three months after intervention

Method of measurement

Sphygmomanometer in millimeters of mercury

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 2 pills containing 200 mg date seed powder for 3 months

Category

Treatment - Drugs

2

Description

Control group: 2 pill containing 200 mg Lactose-free milk powder for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Nutrition and Diet Clinics

Full name of responsible person

Dr Siavash Babajafari

Street address

Central building of Shiraz University of Medical Sciences, Zand St, Shiraz.

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Postal code

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Phone

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mary.hashemzadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nutrition Sciences Reaserch Center, Shiraz University Of Medical Sciences

Full name of responsible person

Dr Siavash Babajafari

Street address

Central building of Shiraz University of Medical Sciences, Zand St, Shiraz.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nutrition Sciences Reaserch Center, Shiraz University Of Medical Sciences

Proportion provided by this source

70

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

Shiraz University of Medical Sciences

Full name of responsible person

Maral Hashemzadeh

Position

student

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Asma Kazemi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Maral Hashemzadeh

Position

student

Latest degree

Master

Other areas of specialty/work

Nutrition

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only a section of the data, such as primary outcomes information or the like, will be shared.

When the data will become available and for how long

Access period start 6 months after results publishing

To whom data/document is available

The obtained data from current study will be available only for working researchers in academic and scientific institutions.

Under which criteria data/document could be used

Six months after the published papers from this study, the obtained data will be available to the researchers for further analysis.

From where data/document is obtainable

Applicants can be communicated to correspond author by e-mail or postal address to receive the requested data. Postal address: Nutrition Research Center, Shiraz university of Medical Sciences, KHalili St, Shiraz. Cell phone:00987136122283.Email address:Nutrition_rs@sums.ac.ir

What processes are involved for a request to access data/document

publishing in scientific- research journals Applicants will be given access to the obtained data from current study by sending an email to the correspond author.

Comments