

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the The Effect Of Evening Primrose On Blood Sugar And Lipid Profile In Pre-Diabetic Menopausal Women Referred To Rafsanjan Comprehensive Health Services Centers In 1397

Protocol summary

Study aim

Determination of the Effect of Flower Magnetic Capsule on Blood Glucose and Lipid Profile in Pre-Diabetic Postmenopausal

Design

Through the sampling available to postmenopausal women who have the criteria for entering the study, they describe the research conditions and, if they wish, they will receive written consent. And the participants are assigned to the intervention and control groups by simple randomization method.

Settings and conduct

pre-diabetic postmenopausal women referring to comprehensive health centers in Rafsanjan.

Participants/Inclusion and exclusion criteria

written consent of the company in the study Pre-diabetic women Non-use of alcohol, tobacco and narcotics Lack of HRT at present Non-use of supplementary extract of Maghrib flower Women who have been at least 12 months since their last menstruation. Lack of chronic mental illness No use of blood glucose suppressants

Intervention groups

For participating people FBS and HbA1C test is requested . After the results are announced, for women with FBS = 100-125, tests for HLD, LDL, TG and cholesterol are requested. Participants were randomly assigned to intervention and control groups. Each participant will receive 30 capsules (Maghreb flower or placebo) with the daily administration of 2 capsules (1000 mg / day in the morning and at night) and a daily intake form. Demographics of the participants are also collected using the form of these features. During the study, all participants will be followed up by phone every week to prevent sample loss and to ensure the correct method of use. Also, at the beginning of each month, participants will be given the following capsules by the attendees at the Comprehensive Health Center. After 3 months of

taking capsules, all tests will be re-tested for all participants.

Main outcome variables

FBS , HbA1C, HDH, LDL, TG, Cholestrol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181210041911N2**

Registration date: **2019-08-26, 1398/06/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-26, 1398/06/04**

Update count: **0**

Registration date

2019-08-26, 1398/06/04

Registrant information

Name

Seyede maryam Lotfipur rafsanjany

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

m.lotfi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the The Effect Of Evening Primrose On Blood Sugar And Lipid Profile In Pre-Diabetic Menopausal Women Referred To Rafsanjan Comprehensive Health Services Centers In 1397

Public title
Investigating the The Effect Of Evening Primrose On Blood Sugar And Lipid Profile In Pre-Diabetic Menopausal Women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
written consent of the company in the study Pre-diabetic women (fasting blood glucose 125-100 mg / dl) Non-use of alcohol, tobacco and narcotics . Lack of HRT at present Non-use of supplementary extract of Maghrib flower Women who have been at least 12 months since their last menstruation Lack of chronic mental illness No use of blood glucose suppressants
Exclusion criteria:
Need to use insulin No proper use of the capsule Sensitization to the capsule Mistake in the dosage of medication for 2 consecutive days Unwillingness to continue participating in the study at any time of the research

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: 82

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is performed in this study by simple randomization. To assign individuals to each drug and drug group, participants who have signed a consent form to participate in the study are asked to draw in one. Be divided into groups A and B.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In order to inform the participants, researcher and analyst, the pharmaceutical manufacturer (Barij Essen) will receive information about the shape, size and color of the capsule and will be asked from the placebo company (Zahrawi) to make placebo capsules in

accordance with the characteristics Drug should be provided. Then, the person who is not involved in the research is asked to pack the capsules in two different types, identifying each category with letters A and B. After completing the sampling and doing the analysis, the person is asked to specify the type of each categories.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rafsanjan University of Medical Sciences

Street address

Nursing avenue, Rafsanjan University of Medical Sciences

City

rafsangan

Province

Kerman

Postal code

7718796755

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.RUMS.REC.1397.173

Health conditions studied

1

Description of health condition studied

Blood sugar and lipids in pre-diabetic menopausal women

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Percentage of people with abnormal HDL

Timepoint

Measurement of before intervention and 3 months after intervention

Method of measurement

Laboratory values

2

Description

Percentage of people with abnormal LDL

Timepoint

Measurement of before intervention and 3 months after intervention

Method of measurement

Laboratory values

3

Description

Percentage of people with abnormal TG

Timepoint

Measurement of before intervention and 3 months after intervention

Method of measurement

Laboratory values

4

Description

Percentage of people with abnormal Cholesterol

Timepoint

Measurement of before intervention and 3 months after intervention

Method of measurement

Laboratory values

Secondary outcomes

1

Description

FBS levels

Timepoint

3 month after intervention

Method of measurement

Laboratory values

2

Description

HDL levels

Timepoint

3 month after intervention

Method of measurement

Laboratory values

3

Description

LDL levels

Timepoint

3 month after intervention

Method of measurement

Laboratory values

4

Description

TG levels

Timepoint

3 month after intervention

Method of measurement

Laboratory values

5

Description

Cholesterol levels

Timepoint

3 month after intervention

Method of measurement

Laboratory values

Intervention groups

1

Description

Intervention group: After measuring the levels of FBS, HbA1C, HDL, LDL, TG and cholesterol, the participants consumed 2 of Evening Primrose capsules for 3 months (At night and in the morning a capsule).After 3 months of intake, blood sugar and lipids are measured again.

Category

Treatment - Drugs

2

Description

Control group: After measuring the levels of FBS, HbA1C, HDL, LDL, TG and cholesterol, the participants consumed 2 of placebo capsules for 3 months (At night and in the morning a capsule).After 3 months of intake, blood sugar and lipids are measured again

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

To Rafsanjan Comprehensive Health Services

Full name of responsible person

Asma Absalan

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Nursing Ave, Motaahhari Blvd Faculty of Nursing, Midwifery, Rafsanjan

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Email

asma.absalan.a@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shamsi Zadeh

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Nursing Ave, Motaahhari Blvd Faculty of Nursing, Midwifery, Rafsanjan

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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

Vice chancellor for research, Rafsanjan 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**

Rafsanjan University of Medical Sciences

Full name of responsible person

Asma Absalan

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Seyyedeh Maryam Lotfipour Rafsanjani

Position

Academic instructor

Latest degree

Master

Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available