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 peopleFBS 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
Street address
Nursing Ave, Motaahhari Blvd Faculty of Nursing,Midwifery,Rafsanjan
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Phone
+98 34 3425 5900
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
Street address
Nursing Ave, Motaahhari Blvd Faculty of Nursing,Midwifery,Rafsanjan
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Phone
+98 34 3425 5900
Email
asma.absalan.a@gmail.com
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
Street address
Nursing Ave, Motaahhari Blvd Faculty of Nursing,Midwifery,Rafsanjan
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Phone
+98 34 3425 5900
Email
asma.absalan.a@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Seyyedeh MarymLotfipour Rafsanjani
Position
Academic instructor
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Nursing Ave, Motaahhari Blvd Faculty of Nursing,Midwifery,Rafsanjan
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Phone
+98 34 3425 5900
Email
maryam_lotfypur@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Seyyedeh MarymLotfipour Rafsanjani
Position
Academic instructor
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Nursing Ave, Motaahhari Blvd Faculty of Nursing,Midwifery,Rafsanjan
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Phone
+98 34 3425 5900
Email
maryam_lotfypur@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
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