Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

The effect of oral capsules Rosa damascena mill extract on menopausal symptoms

Protocol summary

Study aim
Determining of the effect of oral capsule of Rosa damascena mill extract on menopausal symptoms
Design
The clinical trial has a control group, with parallel groups, triple blind, randomized, phase 3 and is performed on 78 postmenopausal women who have been selected as available method and persons randomly enter to each groups by random sequence.
Settings and conduct
Gorgan Health Centers
Participants/Inclusion and exclusion criteria
Minimum elementary education, age 45-60 years, normal menopause, being married and living with her husband, having sexual intercourse in the past month, initial score of Menopause Rating Scale at least 5, no use of effective herbal and chemical drugs on menopausal symptoms in the past 6 months, no use of effective complementary medicine on menopausal symptoms in the past 6 months, no history of cancer, no known and treated medical conditions that effective on study results, no drug addiction and smoking and alcohol consumption
Intervention groups
Intervention group used Rosa damascena mill extract oral capsule and control group received placebo containing Avisel powder.
Main outcome variables
Severity of menopausal symptoms

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210208050295N1**
Registration date: **2021-03-03, 1399/12/13**
Registration timing: **prospective**
Last update: **2021-03-03, 1399/12/13**
Update count: **0**
Registration date
2021-03-03, 1399/12/13

Registrant information
Name
Zohre Gholinezhad
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-21, 1400/02/01
Expected recruitment end date
2021-09-23, 1400/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of oral capsules Rosa damascena mill extract on menopausal symptoms

Public title
The effect of Rosa damascena mill on menopausal symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Having a minimum education in primary school Age 45 to 65 years old Having a normal menopause (stopping menstruation for at least one year after 45 years old, without interfering with pregnancy and lactation, surgery, medication and pathology) Married and living with her husband Having sexual intercourse in the last month Obtained at least 5 score from the initial MRS Lack of known and treated medical diseases which affect the results of the study (cardiovascular, liver, kidney, chronic lung disorders, thyroid, neurology and psychiatry diseases, musculoskeletal, pelvic prolapse, urinary disorders and neurological diseases known and treated) No history of cancer

Exclusion criteria:

Drug addiction, smoking and alcohol abuse Taken medicine that improve menopausal symptoms in the last 6 months (Such as estrogen and progesterone, GnRH agonists and antagonists, clonidine, gabapentin, serotonin and norepinephrine inhibitors, paroxetine, venlafaxine, vitamin E, methyldopa, naloxone and tibolone) Use of complementary medicine to improve menopausal symptoms (such as herbs, acupuncture and acupressure) during the last 6 months Women professional athletes or women with severe mobility limitations who are unable to do housework

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done in all 8 comprehensive centers of health services in Gorgan. The researcher is present in each of these centers and based on the selecting the research unit checklist, women who are eligible to enter the study are selected as available method. The capsule containing Rosa damascena mill extract and placebo is provided to the researcher by the pharmacist consulting professor in similar forms with two different codes and only the pharmacist consulting professor is aware of the codes. Individuals eligible for the study will be randomly assigned to the drug or placebo group by random sequence.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to blind the capsule of Rosa damascena mill extract and placebo in similar shapes and completely identical packages are provided to the researcher. Each of them has a code that only the pharmacist consultant knows. Eligible individual are randomly assigned to drug or placebo groups by random sequence. Therefore until the end of the study research units, researcher and statistician will not be aware of the codes related to drug and placebo groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Nursing and Midwifery, Mashhad University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Doctora Crossroads, Daneshgah Street

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Mashhad

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Razavi Khorasan

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9137913199

Approval date

2021-02-13, 1399/11/25

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.084

Health conditions studied

1

Description of health condition studied

menopausal symptoms

ICD-10 code

GA30.00

ICD-10 code description

Any condition of the genital system affecting females, caused by pathological changes associated with the perimenopausal period, such as the permanent cessation of menstruation and infertility. Includes: Symptoms such as flushing, sleeplessness, headache,

Primary outcomes

1

Description

severity of menopause symptoms

Timepoint

At the beginning of the study (before the start of the study) and at the beginning of weeks 4 and 8 after the

start of the study

Method of measurement

Menopause raring scale

Secondary outcomes

1

Description

Depression, anxiety and stress in menopausal women

Timepoint

At the beginning of the study (before the start of the study) and at the beginning of weeks 4 and 8 after the start of the study

Method of measurement

Depression, Anxiety and Stress Scale

2

Description

Quality of sleep in menopausal women

Timepoint

At the beginning of the study (before the start of the study) and at the beginning of weeks 4 and 8 after the start of the study

Method of measurement

Pittsburgh Sleep Quality Index

3

Description

Sexual function in menopausal women

Timepoint

At the beginning of the study (before the start of the study) and at the beginning of weeks 4 and 8 after the start of the study

Method of measurement

Female sexual function index

Intervention groups

1

Description

Intervention group: In this group, research units take a 500 mg capsule containing Rosa damascena mill hydro-alcoholic extract every 12 hours for 8 weeks. These capsules are prepared in the Department of Medicinal Plants Pharmacology of Mashhad University of Medical Sciences. According to the studies presented on Rosa damascena mill, 71 mg / kg per day of the alcoholic extract of this plant will not be toxic to humans.

Category

Treatment - Other

2

Description

Control group: In this group, research units take a placebo capsule every 12 hours for 8 weeks. Each of these capsules contains 500 mg of Avisel powder and is made with the appearance and packaging similar to Rosa damascena capsule in the Department of Medicinal Plants of Mashhad University of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in Gorgan

Full name of responsible person

Fatemeh zahra Karimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Mashhad 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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