

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

gholinezhadz982@gmail.com

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

City

Mashhad

Province

Razavi Khorasan

Postal code

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 rating 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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Razi St. - Shahid Rajaei St.

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Web page address

<http://www.goums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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

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

Mashhad University of Medical Sciences

Full name of responsible person

Zohre Gholinezhad

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Student

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Fatemeh zahra Karimi

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Associate Professor

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Province

Razavi Khorasan

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