Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effect of Rose (Rosa damascena) Capsule on the Severity of Depression and Anxiety in Menopausal Women

Protocol summary

Study aim
Determination of the effect of rosa damasena flower capsule on the severity of depression and anxiety in menopausal women

Design
Clinical trial with blind, double blind, parallel, randomized, control group with a sample size of 110 patients who participated in intervention for 40 days.

Settings and conduct
Health centers affiliated to Shahid Beheshti University of Medical Sciences were randomly selected and then two centers were randomly selected. 110 people (55 in the intervention group and 55 in the control group) will be selected. For sealing the medicine, the capsule of rose in the envelope will be placed next to the placebo. For example, the envelope A contains 500 mg capsules of rose and B envelopes containing placebo capsules. The researcher and the units of the research are not codifying and that each envelope contains what drug. The simple random sampling method by coin tossing assigns the envelope A to the intervention centers and envelope B to the control centers.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range 60-45 yr. Having normal blood pressure, no history or history of breast, uterine, aneurysm and methotrexing, abnormal vaginal bleeding, liver disease, hyperthyroidism, lack of history of hysterectomy or ovariectomy, no physical or mental illness Known. Non-compliance criteria: Sensitization to herbal medicines, smoking and alcohol.

Intervention groups
The participants are 110 people. The intervention group is 55. The study examines the effect of rose capsule on depression and anxiety in these patients. The control group is 55 who are studying the effect of placebo on depression and anxiety.

Main outcome variables
Anxiety, Depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190305042936N1**
Registration date: **2019-07-28, 1398/05/06**
Registration timing: **prospective**

Last update: **2019-07-28, 1398/05/06**
Update count: **0**

Registration date
2019-07-28, 1398/05/06

Registrant information
Name
Qamar Riazi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-23, 1398/06/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Rose (Rosa damascena) Capsule on the Severity of Depression and Anxiety in Menopausal Women

Public title

The effect of Rose (Rosa damascena) Capsule on the Severity of Depression and Anxiety in Menopausal Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Menopausal women aged 45-60 years Having normal blood pressure Not having a historyof BreastCancer, uterine, endometrial hyperplasia, abnormal vaginal bleeding, liver disease, hyperthyroidism Not having a history of hysterectomy or ovariectomy Not having physical (Diabet) or psychiatric illnesses Do not use rose or dried rose extract

Exclusion criteria:

Sensitization to herbal medicines Smoking and Alcohol

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: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the health centers affiliated to Shahid Beheshti University of Medical Sciences who are most referred to, two centers will be randomly selected. 110 people (55 in the intervention group and 55 in the control group) will be selected. In order to blow up the medicine, the rose capsule in the envelope will be placed adjacent to the placebo to relieve the scent of the roses to the placebo capsule. The investigator and the research units are not aware of the coding and the fact that each envelope contains any drug. Using a simple random sampling method by throwing a coin, a sealed envelope containing the drug will be assigned to one of the centers and another sealed envelope containing the placebo to the next center. Postmenopausal women, as a research sample, will be in one of the relevant groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blow up the medicine, the capsule of rose in the envelope will be placed in the immediate vicinity of the placebo to transfer some of the rosy smell to the placebo capsule. The drugs are encoded in the pharmacy department of Shahid Beheshti University of Medical Sciences. The researcher and the research units are not aware of the coding and the fact that each envelope contains the drug, and only the pharmacist advised of the encoding of the envelopes and the type of medication.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Valiasr Street

City

Tehran

Province

Tehran

Postal code

: 1985717443

Approval date

2019-04-15, 1398/01/26

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.033

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.9

ICD-10 code description

Depressive episode , unspecifide

2

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Depression Score in Beck Questionnaire

Timepoint

Before the start of the study, 20 days later, 40 days later

Method of measurement

Beck questionnaire

2

Description

Anxiety Scale in the Spielberg Burner Questionnaire

Timepoint

Before the start of the study, 20 days later, 40 days later

Method of measurement

Spielberger questionnaire

Secondary outcomes

1

Description

Quality score

Timepoint

At the beginning of the study, 20 days later, 40 days after starting the dose.

Method of measurement

Quality of Life questionnaire

Intervention groups

1

Description

"Intervention group:" Menopausal women aged between 45-60 years old referred to Shahid Beheshti University of Medical Sciences, who received 1000 mg (two 500 mg capsules of rose, containing 500 mg of powdered dried rice with active ingredient (citronella) Vengerinol) take daily, twice, every 12 hours, in the morning and night after a meal for 40 days. "Control group: Menopausal women aged between 45-60 years old referring to Shahid Beheshti University of Medical Sciences 1000 mg (Two 500 mg starch capsules) every 12 hours, twice daily, morning and evening, after eating for 40 days. Capsules at the School of Pharmacy, University of Medical Sciences When is the martyr Beheshti prepared.

Category

Treatment - Drugs

2

Description

Control group: Menopausal women aged between 45-60 years old referring to Shahid Beheshti University of Medical Sciences 1000 mg (Two 500 mg starch capsules) every 12 hours, twice daily, morning and evening, after eating for 40 days. Capsules at the School of Pharmacy, University of Medical Sciences When is the martyr Beheshti prepared.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

shobeir health center

Full name of responsible person

Qamar Riazi

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Recruitment center

Name of recruitment center

Seraj health center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahrokh Dolatian

Street address

Faculty of Nursing and Midwifery, Shahid Behesti,Valiasr Street shti University of Medical Sciences

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Qamar Riazi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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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