

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 Riaz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4447 8576

Email address

riazi.qamar2430@gmail.com

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		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.	
Public title	The effect of Rose (Rosa damascena) Capsule on the Severity of Depression and Anxiety in Menopausal Women	Placebo	Used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: Menopausal women aged 45-60 years Having normal blood pressure Not having a history of Breast Cancer, 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	Other design features	
Age	From 45 years old to 60 years old	Secondary Ids	empty
Gender	Female	Ethics committees	
Phase	3	<u>1</u>	
Groups that have been masked	- Participant - Care provider - Investigator - Outcome assessor - Data analyser	Ethics committee	
Sample size	Target sample size: 110	Name of ethics committee	Ethics Committee of Shahid Beheshti University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	Shahid Beheshti University of Medical Sciences, Valiasr Street
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.	City	Tehran
Blinding (investigator's opinion)	Double blinded	Province	Tehran
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	Postal code	: 1985717443
		Approval date	2019-04-15, 1398/01/26
		Ethics committee reference number	IR.SBMU.PHARMACY.REC.1398.033
		Health conditions studied	
		<u>1</u>	
		Description of health condition studied	Depression
		ICD-10 code	F32.9
		ICD-10 code description	Depressive episode , unspecifide
		<u>2</u>	
		Description of health condition studied	Anxiety
		ICD-10 code	F06.4
		ICD-10 code description	Anxiety disorder due to known physiological condition
		Primary outcomes	
		<u>1</u>	
		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

Street address

Shobeir health center, Ghanbari St, Khorasan Square, Tehran

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Recruitment center

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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

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Faculty of Nursing and Midwifery, Shahid Beheshti, 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
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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