

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of rose oil essence on the sexual dysfunction of menopausal women

Protocol summary

Study aim

Determining the effect of rose essential oil on sexual dysfunction and quality of life in postmenopausal women

Design

This study is a double-blind randomized clinical trial on 90 postmenopausal women. In this study, the placebo was made in the same shape, size, and color as the main drug, so the triple-blind method will be used. The intervention is in the form of medication or placebo for 8 weeks and daily consumption of two capsules.

Settings and conduct

This study will be performed on women referring to the health centers of Tabriz University of Medical Sciences. Made in the same shape and synchronously with the drug for placebo blinding. The random allocation method will be used for groups and opaque envelopes will be used to hide random allocation in numbered consecutive packets.

Participants/Inclusion and exclusion criteria

Women with normal menopause, Being between 45 and 65 years old, married, at least one year old and up to 5 since menopause Do not use any medication that affects a person's sexual response, including hormonal, herbal, or complementary medications to relieve menopausal symptoms. Reluctance to continue participating in research Do not take medication or placebo for more than 6 days during the study Use of other treatment and intervention methods to reduce menopausal symptoms during research other than the instructions provided by the researcher The occurrence of unfortunate events such as loss of spouse or close relatives during the research period

Intervention groups

Intervention group: Rose essential oil in the form of soft capsules containing 15 mg Control group: placebo with a similar appearance and containing only sesame oil or soybean oil

Main outcome variables

Overall sexual function score; Overall quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190818044553N1**

Registration date: **2020-07-22, 1399/05/01**

Registration timing: **prospective**

Last update: **2020-07-22, 1399/05/01**

Update count: **0**

Registration date

2020-07-22, 1399/05/01

Registrant information

Name

Rana Dousti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3553 7654

Email address

rana.doosty2@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of rose oil essence on the sexual dysfunction of menopausal women		containing the group of soft red capsules and placebo It will be placed inside the envelopes.	
Public title	The effect of rose oil essence on the sexual dysfunction of menopausal women	Blinding (investigator's opinion)	Triple blinded
Purpose	Supportive	Blinding description	Rose essential oil is available in soft capsules containing 15 mg of essential oil (standardized based on the presence of at least 7.5 mg of citronellol in each soft capsule) based on sesame oil or soybean oil. The placebo will have a similar appearance and only contain sesame or soybean oil, so that the samples and the service provider, the researcher is unaware of the contents of the capsules, and the researcher analyzing the results of the analysis will be unaware of the allocation of individuals in groups.
Inclusion/Exclusion criteria	Inclusion criteria: Women with normal menopause, Being between 45 and 65 years old, married, at least one year old and up to 5 since menopause Do not use any medication that affects a person's sexual response, including hormonal, herbal or complementary medications to relieve menopausal symptoms. No known mental health problems or systemic illness affecting sexual function Do not take any sedatives or antidepressants, aspirin or anticoagulants Lack of sensitivity to herbal medicines Absence of digestive disorders such as nausea, vomiting, nausea and vomiting No addiction or smoking having a minimum literacy in order to complete the questionnaire No accidents at least in the last 6 months Exclusion criteria: Creating any sensitivity to the essential oils used in this research Occurrence of any disease during this study that interferes with the results of this study. Reluctance to continue participating in research Do not take medication or placebo for more than 6 days during the study Use of other treatment and intervention methods to reduce menopausal symptoms during research other than the instructions provided by the researcher Occurrence of traumatic events such as loss of spouse or close relatives during the research period	Placebo	Used
Age	From 45 years old to 65 years old	Assignment	Parallel
Gender	Female	Other design features	
Phase	3	Secondary Ids	empty
Groups that have been masked	- Participant - Care provider - Investigator - Outcome assessor - Data analyser - Data and Safety Monitoring Board	Ethics committees	
Sample size	Target sample size: 90	1	
Randomization (investigator's opinion)	Randomized	Ethics committee	
Randomization description	The selected samples will be randomly assigned using a computer random number table through blocks of 4 and 6 to receive the desired treatment in both groups of soft capsules, red and placebo, and will be assigned according to the assigned group. On closed opaque envelopes, which will be written by a person not involved in the selection of research subjects and data collection, consecutive numbers will be written by the same person in accordance with the assigned group of glasses	Name of ethics committee	Ethics Committee of Tabriz University of Medical Sciences
		Street address	Tabriz, Azadi St., Golgasht St., Tabriz University of Medical Sciences, Central Building No. 2, Third Floor, Research Deputy
		City	tabriz
		Province	East Azarbaijan
		Postal code	00984113357311
		Approval date	2020-07-05, 1399/04/15
		Ethics committee reference number	IR.TBZMED.REC.1399.342
		Health conditions studied	
		1	
		Description of health condition studied	Sexual Dysfunction
		ICD-10 code	F52
		ICD-10 code description	Sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

sexual function

Timepoint

before and 4 weeks after intervention, 8 weeks after intervention

Method of measurement

Female Sexual Function Index Questionnaire

2

Description

Quality of Life

Timepoint

Before and 4 weeks after intervention, 8 weeks after intervention

Method of measurement

Menopause Quality Of Life Questionnaire (MENQOL)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Soft capsules containing 15 mg of essential oil (standardized based on the presence of at least 7.5 mg of citronellol in each soft capsule) based on sesame oil or soybean oil twice daily oral for 8 weeks. Made in the laboratory of the Faculty of Medicine, Tabriz University of Medical Sciences.

Category

Treatment - Drugs

2

Description

Control group: Placebo with similar appearance and containing only sesame oil or soybean oil

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Community Health Centers of Tabriz

Full name of responsible person

Rana Dousti

Street address

Tabriz's Community Health Centers

City

Tabriz

Province

East Azarbaijan

Postal code

5143814998

Phone

+98 41 3444 0057

Email

rana.doosty2@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mahammad Samiei

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

Samiei.moh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Rana Dousti

Position

PHD Student Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery
Street address
Faculty of Nursing & Midwifery, South Shariati street
City
Tabriz
Province
East Azarbaijan
Postal code
5155884818
Phone
98 41365706391
Email
rana.doosty2@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Rana Dousti
Position
Phd Student Midwifery
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing & Midwifery, South Shariati street
City
Tabriz
Province
East Azarbaijan
Postal code
5155884818
Phone
98 41365706391
Email
rana.doosty2@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Rana Dousti
Position
Phd Student Midwifery
Latest degree

Master
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing & Midwifery, South Shariati street
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6770
Email
rana.doosty2@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

The results of the clinical study will be published in the form of an article

When the data will become available and for how long

Immediately after printing the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific use with reference to the article

From where data/document is obtainable

Rana dousti Email

What processes are involved for a request to access data/document

Up to one week after correspondence by email

Comments