Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Public title

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

Purpose

Supportive

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

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

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 containing the group of soft red capsules and placebo It will be placed inside the envelopes.

Blinding (investigator's opinion)

Triple blinded

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.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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 Midwfery
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 Midwfery
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