Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of Melissa officinalis capsule on the sexual function of Menopause women

Protocol summary

Study aim
Determining the effect of Melissa capsules on sexual function of postmenopausal women

Design
A clinical trial with a control group. with parallel groups, triple blind, randomized, phase 3 on 100 patients. Excel software is used for randomization.

Settings and conduct
The researcher selects four centers from the comprehensive health service centers affiliated to SBMU located in the north and east of Tehran by simple random sampling, then eligible postmenopausal women are attended. The informed consent form and relevant questionnaires are completed. Women are randomly assigned to groups 1 or 2 using Excel software in the same order as they enter the study and each group is given a medicine. The researcher, the samples, and the statistical consultant are unaware of what medicine each envelope contains except for pharmaceutical consultant. After the completion of the two-month period, the FSFI questionnaire is completed again because it measures sexual function in the previous month, it is completed again one month after the end of the course. Finally, the data is analyzed by a statistical consultant.

Participants/Inclusion and exclusion criteria
in Iranian cases, at least one year had passed since their menses, do not has hormone replacement therapy, has sexual activity, menopausal women and their husband known for no mental illness, no addiction to smoking or drugs, not acquire depression and anxiety, unknown for any chronic diseases, is not allergenic to medicinal plants and gluten, If cases show sensitivity to Melissa capsules, has not used capsules for two days or more, hasn't taken regularly and the person is reluctant to continue the treatment are removed.

Intervention groups
In intervention group, the samples consumed one Melissa capsule daily, and in the control group, the capsule containing dry bread was consumed for two months.

Main outcome variables
Sexual function score.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230831059313N1**
Registration date: **2023-11-02, 1402/08/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-02, 1402/08/11**
Update count: **0**

Registration date
2023-11-02, 1402/08/11

Registrant information
Name
Hamide Ahmadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 3669 2645
Email address
hamideahmadi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-22, 1402/07/30

Expected recruitment end date
2024-03-18, 1402/12/28

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Melissa officinalis capsule on the sexual function of Menopause women

Public title

Investigating the effect of Melissa officinalis capsule on the sexual function of Menopause women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Be Iranian. At least be literate in reading and writing. At least one year has passed since their menopause. Have a married life with her husband. Not willing or required to use hormone replacement therapy. According to Miss Menopause don't use any chemical or herbal medicine to treat your problem. have sexual activity. Do not use herbal teas while taking medicines.

Exclusion criteria:

Have speech, hearing or mental disorders that prevent communication with the researcher. Have undergone hysterectomy and ovariectomy, cystocele and rectocele, and mastectomy. Have a history of known chronic diseases such as high blood pressure, diabetes, asthma, weakening the immune system, etc. Her husband of a menopausal woman have sexual problems. Menopausal women and their husbands are known to have mental illness. Addicted to smoking or drugs. A special event or incident that constitutes a crisis in their life, such as the death of a loved one, incurable illness in family members, change of residence, loss of job has occurred since 6 months ago. Have a history of allergy to medicinal plants. Have a history of endometrial cancer and other estrogen-related cancers in first-degree relatives. Have a history of gluten sensitivity.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

First, in order to select health service centers, the researcher needs to select four centers by simple random sampling. Random numbers function of Excel software is used to randomize the samples into intervention and control groups. to this extent, the numbers represented the samples are sorted from 1 to 100 then written in order in the first column and in the next column, the numbers 1 and 2 are randomly placed in front of each sample. Finally, the samples are divided into two groups in the same order as they enter the study.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is a triple-blind randomized clinical study. Therefore, the researcher, the research units, and the statistics consultant professor are not aware of the coding and what sort of medicine each package contains and only the pharmaceutical consultant of the research is aware of the coding of the envelopes and the type of drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Schools of Pharmacy, Midwifery Nursing - Shahid Beheshti University of Medical S

Street address

13th floor, Block A, Headquarters of Ministry of Health, Treatment and Medical Education, Simai Iran St, between South Flamak and Zarafshan, Quds town (west), Tehran

City

Tehran

Province

Tehran

Postal code

ethics@receaech.ac.i

Approval date

2023-08-01, 1402/05/10

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.074

Health conditions studied

1

Description of health condition studied

Sexual function of Menopause women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual function score in female sexual function index questionnaire

Timepoint

At the beginning of the study (before the start of the intervention) and immediately after the end of the intervention and one month after the end of the intervention

Method of measurement

Female Sexual Function Index Questionnaire

Secondary outcomes

1

Description

Sexual satisfaction score

Timepoint

Before the start of the intervention, immediately after the end of the intervention and one month after the end of the intervention.

Method of measurement

Female sexual Function Index Questionnaire

Intervention groups

1

Description

Intervention group: In this research, the intervention group consumes Melissa capsules. These capsules contain 500 mg of Melissa plant extract powder. These capsules are prepared in the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences. In this way, the purchased plant is extracted by the pharmaceutical consultant. It is made into a powder and poured into capsules similar to a placebo and one capsule per day is consumed by a menopausal woman for two months.

Category

Treatment - Drugs

2

Description

Control group: In this study, the control group uses a placebo. Placebo means edible capsules containing dry bread powder And these capsules are adapted to Melissa capsules in terms of shape and size. They are prepared in the laboratory of the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences, by the pharmaceutical consultant professor. also, the capsules are placed along side to each other so that they smell similar and then they are provided to the samples in similar envelopes. One capsule is taken daily for two months by a menopausal women.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nader Health Comprehensive Service Center

Full name of responsible person

Panthea Mahdavi

Street address

Esfandani Street, Jashnvare Street, Tehran Pars

City

Tehran

Province

Tehran

Postal code

1654887171

Phone

+98 21 7732 2277

Email

mbsh@sbmu.ac.ir

2

Recruitment center

Name of recruitment center

Kadus Comprehensive Health Service Center

Full name of responsible person

Ahmad Ali Dad Khodei

Street address

Sojdeh Street, Jashnvare Street, Tehran Pars

City

Tehran

Province

Tehran

Postal code

1655948843

Phone

+98 21 7770 9141

Email

mbsh@sbmu.ac.ir

3

Recruitment center

Name of recruitment center

Comprehensive health service center of Ba'ath al-Nabi

Full name of responsible person

Arin Mansouri

Street address

7th street, 15 meters third, Afsarieh

City

Tehran

Province

Tehran

Postal code

1743643751

Phone

+98 21 7743 0048

Email

shargh.pr@sbmu.ac.ir

4

Recruitment center

Name of recruitment center
Taqavi Comprehensive Health Service Center
Full name of responsible person
Seyed Mehdi Seyed Darabi
Street address
Porzargar Alley, Aghajanlu St., Mujahideen St.,
City
Tehran
Province
Tehran
Postal code
1157714111
Phone
+98 21 3356 4646
Email
shargh.pr@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Building No. 2, Next to Taleghani Hospital, Erabi St., Student Blvd., Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9780
Email
info@sbmu.ac.ir

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
Hamide Ahmadi
Position
Student
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Shahid Beheshti School of Nursing and Midwifery, The intersection of Hashemi Rafsanjani highway and Valiasr street
City
Tehran
Province
Tehran
Postal code
1996835119
Phone
+98 21 8820 2518
Email
hamide.ahmadi1990@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Elham Zare
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Shahid Beheshti School of Nursing and Midwifery, The intersection of Hashemi Rafsanjani highway and Valiasr street
City
Tehran
Province
Tehran
Postal code
1996835119
Phone
+98 21 8865 5366
Email
elhamzare.phd@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hamide Ahmadi
Position
Student
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No. 10, Mousa Abadi Ave., Emam Khomeini Blvd., Ghaleno., Shahre Rey
City
Tehran
Province
Tehran
Postal code
1996835119
Phone
+98 21 3669 2645
Fax
Email
hamideahmadi@sbmu.ac.ir

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