

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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)

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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
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 ethics@receaeach.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

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Recruitment center

Name of recruitment center

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Full name of responsible person

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3

Recruitment center

Name of recruitment center

Comprehensive health service center of Ba'ath al-Nabi

Full name of responsible person

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4

Recruitment center

Name of recruitment center

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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

Dr. Afshin Zarghi

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Building No. 2, Next to Taleghani Hospital, Erabi St.,
Student Blvd., Shahid Chamran Highway

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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

Hamide Ahmadi

Position

Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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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