

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

comparison of the effect of cinnamon and vitex oral capsules on sexual function in postmenopausal women covered by selected health centers affiliated to shahid beheshti university of medical sciences in 2019

Protocol summary

Study aim

Main goal: Investigating the effect of cinnamon and vitex-agnus capsule on improving the sexual function of postmenopausal women Objective goal: Improving the sexual function of postmenopausal women without the need for hormonal drugs

Design

triple blind clinical trial

Settings and conduct

North Tehran Health Centers

Participants/Inclusion and exclusion criteria

1. Be Iranian. 2. Have at least literacy. 3. Do not have speech, hearing or mental disorders that prevent communication with the researcher. 4. It's been at least a year since they stopped menstruating. 5. Have a married life with your spouse. 6. There is no inclination or obligation to use hormone replacement therapy. 7. According to Ms. Menopause, do not use any chemical or herbal remedies to treat your problem. 8. Have sex. 9. A postmenopausal wife does not have a sexual problem.

Intervention groups

Intervention group: Active drug control group: placebo

Main outcome variables

sexual function, and its domains include: desire, arousal, lubrication, orgasm, satisfaction, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200504047299N1**

Registration date: **2020-07-08, 1399/04/18**

Registration timing: **retrospective**

Last update: **2020-07-08, 1399/04/18**

Update count: **0**

Registration date

2020-07-08, 1399/04/18

Registrant information

Name

Tanya Koliji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 4244 6875

Email address

tanipaezan.koliji@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-29, 1398/11/09

Expected recruitment end date

2020-06-29, 1399/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of cinnamon and vitex oral capsules on sexual function in postmenopausal women covered by selected health centers affiliated to shahid beheshti university of medical sciences in 2019

Public title

comparison of the effect of cinnamon and vitex oral capsules on sexual function in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Be Iranian. 2. Have at least literacy. 3. Do not have speech, hearing or mental disorders that prevent communication with the researcher. 4. It's been at least a year since they stopped menstruating. 5. Have a married life with her spouse. 6. There is no inclination or obligation to use hormone replacement therapy. 7. As menopausal woman sated, do not use any chemical or herbal remedies to treat her problem. 8. Have sexual activity. 9. A postmenopausal wife does not have a sexual problem. 10. They have not undergone hysterectomy and ovariectomy, cystocele, rectocele, and mastectomy. 11. Menopausal women and their spouses do not have a known mental illness. 12. Not addicted to cigarettes or drugs. 13. He has not recently used antidepressants drugs. 14. Have no history of known chronic diseases such as high blood pressure, diabetes, asthma, weaken the immune system, etc. 15. Has no history of allergy to medicinal plants. 16. Do not use herbal teas during medication. 17. Age between 45 and 65 years

Exclusion criteria:

1. Possible sensitivity to capsules 2. Do not take the capsule for a week or more 3. Lack of desire to continue treatment

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Random numbers were used to randomize and assign individuals to groups; randomization using Excel software is as follows: First, in a column, groups are entered as A, B, c, and below, because the number of samples in each group is set to 35 (including the sample fall), so 35, B, A c must be as follows. And they come in regularly. In the opposite column, random numbers are generated using the RAND command. In the next step, using the sort command, random numbers generated from small to large or vice versa are arranged, which causes the order of the groups, c, A, B, to change. Using the new order, people are assigned to different groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is a randomized triple-blind clinical trial, meaning that the researcher, research sample, and statistical consultant professor are unaware of what

drugs each group is taking, or which of the A, B or C envelopes contain which drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid beheshti university of medical science

Street address

No. 58, Raees zاده St., Tehran villa Ave., Satarkhan14

City

tehran

Province

Tehran

Postal code

۱۴۴۴۷۳۴۷۷۹

Approval date

2019-12-10, 1398/09/19

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.243

Health conditions studied

1

Description of health condition studied

اختلال کارکرد جنسی

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

Sexual dysfunction according to the FSFI questionnaire

Timepoint

Before intervention, 2 month after intervention, 3 month after intervention

Method of measurement

FSFI questionnaire

Secondary outcomes

1

Description

Sexual desire

Timepoint

Before intervention, 2 month after intervention, 3 month after intervention

Method of measurement

The Female Sexual Function Index (FSFI) questionnaire

2

Description

Sexual satisfaction

Timepoint

Before intervention, 2 month after intervention, 3 month after intervention

Method of measurement

The Female Sexual Function Index (FSFI) questionnaire

3

Description

Orgasm

Timepoint

Before intervention, 2 month after intervention, 3 month after intervention

Method of measurement

The Female Sexual Function Index (FSFI) questionnaire

4

Description

Arousal

Timepoint

Before intervention, 2 month after intervention, 3 month after intervention

Method of measurement

The Female Sexual Function Index (FSFI) questionnaire

5

Description

Lubrication

Timepoint

Before intervention, 2 month after intervention, 3 month after intervention

Method of measurement

The Female Sexual Function Index (FSFI) questionnaire

6

Description

Pain during intercourse

Timepoint

Before intervention, 2 month after intervention, 3 month after intervention

Method of measurement

The Female Sexual Function Index (FSFI) questionnaire

Intervention groups

1

Description

The intervention group is menopausal women, which will be divided into two groups: oral cinnamon capsules (400 mg) and vitex-agnus capsules (400 mg). The capsules will be provided at the School of Pharmacy of Shahid Beheshti University of Medical Sciences, and postmenopausal women will take 2 capsules a day for 2 months.

Category

Treatment - Drugs

2

Description

The control group is menopausal women who will receive placebo capsules. These capsules were prepared in the Faculty of Pharmacy in Shahid Beheshti University of Medical Sciences and were matched with cinnamon capsules and vitex-agnus in terms of appearance. Samples take 2 of these capsules for 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

North Tehran Health Center

Full name of responsible person

Dr. Nemat alah Mohammadi Nia

Street address

No. 2/16., Eshraghi Ave., shariati St.

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1444734779

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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. Masoumeh Simbar

Street address

Valiasr St., Niayesh Intersection, in front of Shahid Rajaei Heart Hospital, Nursing and Midwifery Faculty

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1985717443
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sbnmf@sbm.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
Tanya Koliji
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Elham Zare
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assistant Professor

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the consequences will be shared

When the data will become available and for how

long

3 month after outcomes

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to perform more accurate clinical trials

From where data/document is obtainable

Nursing and Midwifery Faculty of Shahid beheshti
university of medical science

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

It will be available as soon as possible after requesting information

Comments