Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The efficacy of Jazar capsule, a Persian medicine product, on menopausal symptoms and sexual disorder of menopausal women

Protocol summary

Study aim

The efficacy of Jazar capsule, a persian medicine product, on menopausal symptoms and sexual disorder of menopausal women

Design

Clinical trial with intervention and control (placebo) group, double blind, four-way randomized blocks, with sample size of 90 people in two groups of 45 and 2 month study for each person.

Settings and conduct

The research places˝are Ahmadiyeh clinic, Aboozar clinic, Farmanfarmayan clinic and Emam-Khomeini hospital(Gynecology clinic). In the intervention group, 500 mg Jazar capsule and in the control (placebo) group 500 mg of starch powder capsule, both are prescribed 2 capsules every 12 hours for two months. Both are identical in terms of appearance and packaging, only differentiated through the proprietary codes set by the pharmacist on the box of medicine. The patient and the prescribing researcher are not aware of the codes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married women that their spouses are present at home at least for half of each month; Age between 45-60; No menstrual periods for at least 12 months and no longer than 5 years; Literate or having a literate person at home; Menopause but not due to illness or uterus and ovaries resection; At least 2 hot flashes per day; FSFI ≤ 26; Willing to attend the project; Normal Pap smear during the last two years. Exclusion criteria: Taking other medications to resolve their menopausal signs; Allergy to the medicines of this research; History of serious physical or mental illness; Hormone intake for the past 6 months; Addiction to cigarettes, drugs or alcohol.

Intervention groups

Medicine: Jazar capsule Placebo: starch powder

Main outcome variables

Menopause quality of life, Female sexual function index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180705040349N1**
Registration date: **2018-10-09, 1397/07/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-09, 1397/07/17**
Update count: **0**

Registration date

2018-10-09, 1397/07/17

Registrant information

Name

Sousan Hafizi moori

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8809 7810

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Jazar capsule, a Persian medicine product, on menopausal symptoms and sexual disorder of menopausal women

Public title
The efficacy of Jazar capsule, on menopausal symptoms and sexual disorder of menopausal women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Married women that their spouses are present at home at least for half of each month Age between 45-60 No menstrual periods for at least 12 months and no longer than 5 years literate or having a literate person at home Menopause but not due to illness or uterus and ovaries resection At least 2 hot flashes per day FSFI ≤ 26 Willing to attend the project Normal Pap smear during the last two years
Exclusion criteria:
Sensitivity to the medicine or placebo Use of other medications or other therapies to reduce the menopausal symptoms during the study Hormone intake for the past 6 months Diabetes or other serious illnesses Malignancy history Addiction to cigarettes, drugs or alcohol History of mental illness
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Assignment of patients to study groups is done using Block Randomization method. Samples are divided into intervention and placebo groups based on the random sequence generated by the statistic consultant. A random sequence is generated by random four-way blocks; each block represents four participants. Distribution of placebo and interventions in each block is random but under a condition that there must be two placebos and two interventions in each block. Using this method, the number of samples assigned to each of the groups are equal, so in cases that mid-term analysis is required, the equal number of samples for both groups are available.
Blinding (investigator's opinion)
Double blinded
Blinding description
Medication and placebo are identical in terms of appearance an packaging, only differentiated through the proprietary codes set by the pharmacist on the box of medicine. The patient and the prescribing researcher are not aware of the code. The outcomes of the study are prepared by the researcher who is unaware of the grouping and is blind to the groups and type of medications.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-Chancellor in Research Affairs-Tehran University of Medical Sciences
Street address
No.14, st 9, South Golestan, Shahrak-e-gharb
City
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Province
Tehran
Postal code
1465837744
Approval date
2018-07-04, 1397/04/13
Ethics committee reference number
IR.TUMS.VCR.REC.1397.233

2

Ethics committee
Name of ethics committee
Vice-Chancellor in Research Affairs-Tehran University of Medical Sciences
Street address
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Province
Tehran
Postal code
1465837744
Approval date
2018-07-04, 1397/04/13
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Health conditions studied

1

Description of health condition studied
Menopausal symptoms and sexual disorder of menopausal women
ICD-10 code
N95.1

ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Quality of life
Timepoint
Weeks 4, 8 and 10 after intervention
Method of measurement
Menopause quality of life questionnaire (MENQOL questionare)

2

Description
Sexual function
Timepoint
Weeks 4, 8 and 10th after intervention beginning
Method of measurement
Female sexual function index questionare (FSFI questionare)

Secondary outcomes

1

Description
Vaginal maturation index (VMI)
Timepoint
Before intervention and 10 weeks after intervention beginning
Method of measurement
Pap smear

2

Description
Vaginal PH
Timepoint
Before intervention and 10 weeks after intervention beginning
Method of measurement
PH-meter strip

Intervention groups

1

Description
Intervention group: Jazar capsule 500mg, made by Talaye sabz Tooba company, Including powder of chastetree seeds, fennel seeds and carrot seeds, two capsules in the morning and two at night, after meals, for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: 500mg starch capsule, made by Talaye sabz Tooba company, two capsules in the morning and two at night, after meals, for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahmadiveh clinic Iranian medicine center Corner of Tabari Street
Full name of responsible person
Dr Alireza Abbasian
Street address
No. 27, North Sarparast, Palestine square, Ahmadieh clinic
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Traditional Medicine Clinic, Sarparast Str., Palestine square
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Grant name
Tehran university of medical science
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Sousan Hafizi Moori

Position
PhD student

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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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