

# 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 Imam-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  $\leq$  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)

##### Phone

+98 21 8809 7810

##### Email address

sou\_hafizi@yahoo.com

##### 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  $\leq$  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**

Tehran

**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**

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**Postal code**

1465837744

**Approval date**

2018-07-04, 1397/04/13

**Ethics committee reference number**

IR.TUMS.VCR.REC.1397.233

**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 questionnaire)

### 2

#### Description

Sexual function

#### Timepoint

Weeks 4, 8 and 10th after intervention beginning

#### Method of measurement

Female sexual function index questionnaire (FSFI questionnaire)

## 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

Ahmadvieh clinic Iranian medicine center Corner of Tabari Street

##### Full name of responsible person

Dr Alireza Abbasian

##### Street address

No. 27, North Sarparast, Palestine square, Ahmadvieh clinic

##### City

Tehran

##### Province

Tehran

##### Postal code

1465837744

##### Phone

+98 21 8897 6527

##### Email

sou\_hafizi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Sousan Hafizi Moori

##### Street address

Traditional Medicine Clinic, Sarparast Str., Palestine square

##### City

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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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No. 27 , North Sarparast, West Taleghani

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## Person responsible for scientific inquiries

### Contact

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Latest degree**

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**Other areas of specialty/work**

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**Email**

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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