Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of oral Afrodit drop on sexual function and Menopause Rating Scale in menopausal women referred to selected health centers related to Tehran University of Medical Sciences

Protocol summary

Summary

The objective of the study is to assess the effect of Afrodit oral Capsule on sexual function and Menopause Rating Scale in menopausal women referred to selected health centers affiliated to Tehran University of Medical Sciences. Major inclusion criteria includes: Not having physical and psychological diseases in women and their husbands, having at least one sexual contact during the intervention for 4 weeks and Exclusion criteria includes: Not having sex during the study, Taking any additional medication during the study, Not taking the drug under investigation for more than 4 days during the study.More than 250 volunteered menopausal women will be interviewed using sabastburg sexual function Questionnaire and Menopause Rating Scale. About 70 of those who have sexual dysfunction will be invited to participate in the study and fill in a written consent form. Subjects will be randomly divided into two 35 intervention and control groups. The intervention group will receive Afrodit Capsule, three times a day for 4 weeks and the control group will receive placebo, at the same dose. Sabasburg sexual function Index questionnaire score and will be measured and Menopause Rating Scale compared in the two groups before and 4 weeks after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107122172N11**
Registration date: **2012-03-17, 1390/12/27**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2012-03-17, 1390/12/27

Registrant information

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Simin Taavoni
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Iran University of Medical Sciences
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Recruitment status

Not enough for processing

Funding source

Research Institute for Islamic & Complementary Medicine

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2012-06-01, 1391/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral Afrodit drop on sexual function and Menopause Rating Scale in menopausal women referred to selected health centers related to Tehran University of Medical Sciences

Public title

The effect of oral Afrodit Capsule on sexual function and Menopause Rating Scale in menopausal women referred to selected health centers related to Tehran University of

Medical Sciences

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: At least 1 year past the menopause; have sex at least once during the 4 weeks; Not having known physical or mental illness; having physical and mental health in husband; Having a stable partner before and during intervention; No additional drugs during the study (including hormone therapy or any drugs that affect sexual function) Exclusion criteria: Not having sex during study; not use the Capsules to 4 days during the intervention Exclusion criteria: Not having sex during study; not use the drops to 4 days during the intervention

Age

From **50 years** old to **60 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Institute for Islamic & Complementary Medicine

Street address

No.9, Pirniya1, Ave-Northern Lalehzar, street Jomhoory eslami,Tehran

City

Tehran

Postal code

Approval date

2011-09-17, 1390/06/26

Ethics committee reference number

14537

Health conditions studied

1

Description of health condition studied

sexual disfunctions , menopause symptems, Symptoms of Menopause

ICD-10 code

F52.8, F52

ICD-10 code description

Other sexual dysfunction, not caused by organic disorder or disease,

Primary outcomes

1

Description

sexual function score

Timepoint

before intervention and one mount after intervention

Method of measurement

sanastburg sexual function questionnaire

2

Description

Added at 2013-04-27:Symptoms of Menopause Score

Timepoint

Added at 2013-04-27: before intervention and one mount after intervention

Method of measurement

Added at 2013-04-27: .Primary outcome method of measurement:Menopause Rating Scale(MRS

3

Description

Added at 2013-04-27:

Timepoint

Added at 2013-04-27:

Method of measurement

Added at 2013-04-27:

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group 60 oral Afrodit Capsule tree daily for4 weeks

Category

Treatment - Drugs

2

Description

In control group 60 placebo capsule tree daily for 4

weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam khomeyni health center

Full name of responsible person

Eshtehardi, Shiva

Street address

Saat Square, Old Karaj Road, Ghods City

City

Ghods

2

Recruitment center

Name of recruitment center

Emam Hoseyn health center

Full name of responsible person

Eskandari, Zahrah

Street address

Shahid Alami street, Azadi Square, Old Karaj Road, Ghods City

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Islamic & Complementary Medicine

Full name of responsible person

Dr. Ashrafedin Gooshegir

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No.9, Pirniya1, Ave-Northern Lalehzar, street Jomhoory eslami,Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Institute for Islamic & Complementary Medicine

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Nursing and Midwifery Faculty, tehran University of Medical Sciences

Full name of responsible person

simin Taavoni

Position

M.Sc in Medical Education, M.Sc in Midfwifery Education, Academic Faculty Member & Resaercher

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty