Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

The effect of vitagnus on sexual function of Women 50 to 70 years old Referring to the Retirement center of North Khorasan province

Protocol summary

Study aim
Determining the effect of Vitagnus drops on sexual function of women aged 50-70 years old referring to the retired center of North Khorasan province

Design
Clinical practice is a control group with no parallel groups, two blinds. Using the lottery, the intervention group and the placebo are identified. The sample size is 64. phase II clinical trial.

Settings and conduct
North Khorasan Retirees Association

Participants/Inclusion and exclusion criteria
1- 50-70 year-old women 2-No known psychological illness 3-Lack of emotional stress in the past six months (such as the death of close relatives) 4- In spite of being a spouse and living together with a spouse 5- Absent susceptibility to spices and essential oils 6- Lack of alcohol 7- Not using relaxation methods, hormonal, herbal and nerve drugs 8- Non-participation in similar researc9 l- Absence of a variety of cancers at the time of research 10- Failure to have breast and genital cancer in the past (endometrium, cervix, ovary) 11- Not getting bleeding or spotting 12- Absence of sexually transmitted malformations • 1. Do not use drop for one week • 2. People whose sexual performance is above 23 • 3- Observe spotting or bleeding during research • 4. Use of estrogenic hormone or other herbal drugs of phytoestrogens affect the hormonal status during the research period. • 5. Occurrence of adverse event during research • 6. Sensitization

Intervention groups
The research unit is recommended to use 40 drops of vitagnus or placebo with a cold drink for 2 months at the beginning of the morning. The research unit is trained every two weeks, and at the time of being in the center, the amount of drops to be given until the next visit is required. Also, at the intervals of four, six and eight weeks from the onset of intervention, the sexual function questionnaire for the research unit is completed.

Main outcome variables
Sexual function

General information

Reason for update
Acronym
-

IRCT registration information
IRCT registration number: **IRCT20190528043736N1**
Registration date: **2019-06-12, 1398/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-12, 1398/03/22**
Update count: **0**

Registration date
2019-06-12, 1398/03/22

Registrant information
Name
Robabeh Amini ghalandar abad
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 58 3621 6366
Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-06-10, 1398/03/20
Expected recruitment end date
2019-08-11, 1398/05/20
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitagnus on sexual function of Women 50 to 70 years old Referring to the Retirement center of North Khorasan province

Public title

effect of vitagnus on sexual function of Women 50 to 70 years old

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

50-70 year-old women No known psychological illness Lack of emotional stress in the past six months (such as the death of close relatives) In spite of being a spouse and living together with a spouse Absent susceptibility to spices and essential oils Lack of alcohol Not using relaxation methods Non-use of hormonal, herbal and nerve drugs Non-participation in similar research Absence of a variety of cancers at the time of research Failure to have breast and genital cancer in the past (endometrium, cervix, ovary) Not getting bleeding or spotting Absence of sexually transmitted malformations

Exclusion criteria:

Do not use drop for one week People whose sexual performance is above 23 Observe spotting or bleeding during research Use of estrogenic hormone or other herbal drugs of phytoestrogens affect the hormonal Occurrence of adverse event during research Sensitization

Age

From **50 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Those who have the conditions for entry into the study are given the necessary explanations for the study. A written consent form is signed by the patient and his wife and this way, people enter the study. At first, a demographic and clinical data form is made by the researcher and sexual function of women is completed in the interview. Then, people are classified according to age in four groups: 55-50, 60-55, 65-60 and 65-70 years old. Individuals are assigned code, and the groups are separated and separated by each other, using the lottery of the intervention group and the placebo. People in both groups are homogeneous in terms of age.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the negotiation and conclusion of the contract with the pharmaceutical company Poursina Drosa Vitagnus, along with placebo, the company will supply the research unit. Both the vials and the placebo drops contain the same visual appearance, and will be inscribed only on the glass of the letters A and B.

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IR.NKUMS.REC.1398.007

Street address

No14, Khoram Ave, Molla Sadra Blvd, Bojnourd town

City

bojnourd

Province

North Khorasan

Postal code

9415917533

Approval date

2019-05-19, 1398/02/29

Ethics committee reference number

IR.NKUMS.REC.1398.007

Health conditions studied

1

Description of health condition studied

Sexual dysfunction

ICD-10 code

F52.8

ICD-10 code description

Other sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

sexual function

Timepoint

Comparison of the total sexual function of the units before, 4 weeks, 6 weeks, and 8 weeks after taking Vitagnus drops

Method of measurement

Comparison of sexual function before and after taking Vitagnus drops is measured by Rosen's Sexual Function Questionnaire.

Secondary outcomes

1

Description
Menopause symptoms
Timepoint
At the beginning of the study (before the study) 4 weeks, 6 weeks, 8 weeks
Method of measurement
Demographics and clinical demographic data form

Intervention groups

1

Description
"Intervention group": Intervention group: It is recommended to the research unit that at the beginning of the morning, use 40 drops of vitagnus with a cold drink for 2 months in the morning. The research unit is trained every two weeks and at the time of being in the center, the amount of drops consumed before the next visit is required and thus, people in terms of how the drops are consumed and how much they are consumed By handing the empty glass to the researcher, the drug is examined. Also, at the intervals of four, six and eight weeks from the onset of intervention, the sexual function questionnaire for the research unit is completed.
Category
Treatment - Drugs

2

Description
"Control group": It is recommended to the research unit that at the beginning of the morning, use placebo with a cold drink for 2 months in the morning. The research unit is trained every two weeks and at the time of being in the center, the amount of drops consumed before the next visit is required and thus, people in terms of how the drops are consumed and how much they are consumed By handing the empty glass to the researcher, the drug is examined. Also, at the intervals of four, six and eight weeks from the onset of intervention, the sexual function questionnaire for the research unit is completed.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
North Khorasan Retirees Association
Full name of responsible person
Zohre Abasi
Street address
No14, Khoram Ave, Molla Sadra Blvd, Bojnourd Town
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Bojnourd
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Phone
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Email
r.amini.gh1363@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Assistant Professor of North Khorasan University of Medical Sciences
Full name of responsible person
Seyd Kaveh Hojjat
Street address
Shahriar Ave. from Imam Ali Hospital, Faculty of Medical Sciences, Bojnourd Town
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S.Kavehhojjat@gmail.com
Web page address
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Assistant Professor of North Khorasan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Bojnourd University of Medical Sciences

Full name of responsible person
Zohre Abasi

Position
Consultant

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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N14,Khoram Ave, Molla Sadra Blvd

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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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