Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Effect of Vitex Plant on Female Sexual Function

Protocol summary

Study aim
Determination of the Effect of Vitex plant on the score of sexual function in Women Referring to Alzahra Health Center in Rasht
Design
Clinical trials with control group, with parallel groups, double blind, randomized
Settings and conduct
The subjects were women referring to the women's clinic of Al-Zahra Educational care Center, Rasht, which were selected according to inclusion criteria. After giving explanations to individuals, they are randomly divided. The intervention groups and the investigator do not know how to intervene. The method of intervention is to evaluate the performance of sexual function and its areas at the beginning of the study and 4, 8, 12 and 16 weeks after the intervention using the Women sexual function Index.
Participants/Inclusion and exclusion criteria
All fertile women who referred for Pap smear and were healthy in gynecological and physical examinations and seeking treatment for the improvement and enhancement of sexual function
Intervention groups
Administration of Agnugol tablet containing 2.3-4.8 mg of vitex plant; at first, 4, 8,12 and 16 weeks in intervention group Administration of placebo tablet containing starch 2.3-4.8 mg; at first, 4, 8, 12 and 16 weeks in control group
Main outcome variables
Sexual function

General information

Reason for update
publication of results in two parts
Acronym
IRCT registration information
IRCT registration number: **IRCT20100503003860N36**
Registration date: **2018-12-09, 1397/09/18**
Registration timing: **prospective**

Last update: **2021-01-27, 1399/11/08**
Update count: **2**
Registration date
2018-12-09, 1397/09/18

Registrant information
Name
Gity Ozgoli
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-12-22, 1397/10/01
Expected recruitment end date
2020-05-19, 1399/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Vitex Plant on Female Sexual Function

Public title
Effect of Vitex Plant on Female Sexual Function
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Fertile women 15-44 years who referred for Pap smear Healthy in gynecological and physical examinations Seeking treatment for the improvement and enhancement of sexual function

Exclusion criteria:

single Pregnant and lactating Illiterate / cannot read and write Having a specific illness (thyroid problems, diabetes, psychiatric disorders, hyper-prolactonemia, liver problems, etc.) Stressful event in the last 6 months (death or disease of immediate family member, a major change in lifestyle) of any of the couples Mental problems (illness under the supervision or treatment of a physician) in each of the couples according to the woman's statement Treated for any sexual problems in each of the couples according to the woman's statement Alcohol or drug addiction in each of the couples according to the woman's statement Women whose husbands are unable to have normal sex (e.g., erectile dysfunction or premature ejaculation) Any illness in women, including abnormal bleeding, cervicitis and vaginitis without premenstrual tension and premenstrual syndrome. Taking vitamin supplements or hormonal pills like contraceptives

Age

From **15 years** old to **44 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method and description of each method: In the custody In randomization unit: Individual Randomization tool: Random number function, opaque and closed envelopes How to create random sequence: Generate random number function in Excel software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind the allocation, the pills will be divided into the opaque A and B packets and numbered by the anonymous researcher in the sampling. Participant, clinical caregiver, researcher, and outcome evaluator of the type of intervention will be unaware.

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 Sciences

Street address

Nursing and Midwifery college of Shahid Beheshti University of Medical Sciences, in front of Shahid Rajaee Heart Hospital, Niayesh intersection, Valiasr Avenue, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-11-05, 1397/08/14

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1397.155

Health conditions studied

1

Description of health condition studied

Sexual dysfunction

ICD-10 code

F52.0

ICD-10 code description

Hypoactive sexual desire disorder

Primary outcomes

1

Description

Sexual function

Timepoint

Before the intervention, 4,812 and 16 weeks after the intervention

Method of measurement

Female Sexual Function Index questionnaire

Secondary outcomes

1

Description

Sexual desire score

Timepoint

Before the intervention, 4, 8,12 and 16 weeks after the intervention

Method of measurement

Female Sexual Function Index questionnaire

2

Description
Sexual Arousal Score
Timepoint
Before the intervention, 4, 8,12 and 16 weeks after the intervention
Method of measurement
Female Sexual Function Index questionnaire

3

Description
Orgasm Score
Timepoint
Before the intervention, 4, 8,12 and 16 weeks after the intervention
Method of measurement
Female Sexual Function Index questionnaire

4

Description
Coitus of Pain Score
Timepoint
Before the intervention, 4, 8,12 and 16 weeks after the intervention
Method of measurement
Female Sexual Function Index questionnaire

5

Description
Sexual Satisfaction Score
Timepoint
Before the intervention, 4, 8,12 and 16 weeks after the intervention
Method of measurement
Female Sexual Function Index questionnaire

Intervention groups

1

Description
Intervention group: Administration of Agnugol tablet containing 2.3-4.8 mg of vitex plant; manufactured by Gol Dara Co.; Iran; at 0, 4, 8,12 and 16 weeks
Category
Treatment - Drugs

2

Description
Control group: Administration of placebo tablet containing starch 2.3-4.8 mg; manufactured by Shahid Beheshti Pharmaceutical Faculty; Tehran; Iran; at 0, 4, 8,12 and 16 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Educational care Center
Full name of responsible person
Farnoush Farzi
Street address
Al-Zahra Educational care Center., Namjoo Avenue., Rasht
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin zarghi
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Nursing and Midwifery college of Shahid Beheshti University of Medical Sciences, in front of Shahid Rajaee Heart Hospital, Niayesh intersection, Valiasr Avenue, Tehran
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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
Giti ozgoli
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Thereport plan is still unknown
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available