

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8820 2512

###### Email address

gozgoli@sbmu.ac.ir

##### 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 Rajaei 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, 4,8,12 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

##### **City**

Rasht

##### **Province**

Guilan

##### **Postal code**

41446-54839

##### **Phone**

+98 13 3336 9025

##### **Email**

azzahra@gums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Afshin zarghi

##### **Street address**

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

##### **City**

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##### **Province**

Tehran

##### **Postal code**

1985717443

##### **Phone**

+98 21 8820 2512

##### **Fax**

+98 21 8820 2512

##### **Email**

gozgoli@sbmu.ac.ir

#### **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

Tehran

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+98 218865536671

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g.ozgoli@gmail.com

**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**

Midwifery

**Street address**

Valiasr Avenue, intersection of prayer facing Shahid

Rajae Heart Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

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**Phone**

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**Email**

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**Person responsible for updating data****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.

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Giti Ozgoli

**Position**

Assistant professor, PhD in Reproductive Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Valiasr Avenue, intersection of prayer facing Shahid

Rajae Heart Hospital

**City**

Tehran

**Province****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