

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Determination of the Effect of Vitex plant on the sexual satisfaction in Women

#### Protocol summary

##### Study aim

Determination of the Effect of Vitex plant on the sexual satisfaction 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 satisfaction at the beginning of the study and 4, 8 and 12 weeks after the intervention using the Larson questioner.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include 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 satisfaction. Exclusion criteria include medication that interferes with sexual function

##### Intervention groups

The intervention group includes healthy women of reproductive age receiving Aknogol tablets for three months. The control group consists of healthy women of reproductive age receiving placebo tablets for three months.

##### Main outcome variables

sexual satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190703044086N1**

Registration date: **2019-07-14, 1398/04/23**

Registration timing: **prospective**

Last update: **2019-07-14, 1398/04/23**

Update count: **0**

##### Registration date

2019-07-14, 1398/04/23

##### Registrant information

###### Name

Seyedeh Fatemeh Dalil Heirati

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3336 9224

###### Email address

fatemeh\_heirati@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-23, 1398/05/01

##### Expected recruitment end date

2020-10-14, 1399/07/23

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Determination of the Effect of Vitex plant on the sexual satisfaction in Women

##### Public title

Determination of the effect of Vitex plant on the sexual satisfaction in Women

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion 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 satisfaction

### Exclusion criteria:

single, Pregnant and lactating, 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 **25 years** old to **44 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

## Sample size

Target sample size: **126**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization is done individually by the random number function tool 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 Guilan University of Medical Sciences

##### Street address

Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, Shahid Siadati St., Namjoo Ave

##### City

Rasht

##### Province

Guilan

##### Postal code

41446-66949

#### Approval date

2019-06-26, 1398/04/05

#### Ethics committee reference number

IR.GUMS.REC.1398.147

## Health conditions studied

### 1

#### Description of health condition studied

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 Satisfaction

#### Timepoint

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

#### Method of measurement

Larson questionnaire

## Secondary outcomes

### 1

#### Description

Medicinal effects

#### Timepoint

During and after medication

#### Method of measurement

Ask the patient

## Intervention groups

### 1

#### Description

Intervention group: Administration of Agnugol tablet containing 2.3-4.8 mg of vitex plant; Manufacture of Gol Dara Co.; Iran; at first, 4, 8 and 12 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Administration of placebo tablet containing starch 2.3-4.8 mg; Construction of Shahid Beheshti Pharmaceutical Faculty, Tehran, Iran; at first, 4, 8 and 12 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Al-Zahra hospital

##### Full name of responsible person

Farnoush Farzi

##### Street address

Al-Zahra Hospital, Namjoo Ave

##### City

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##### Province

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##### Postal code

41446-66949

##### Phone

+98 13 3336 9224

##### Email

h\_fertility@gums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Shadman Nemati

##### Street address

Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, Shahid Siadati St., Namjoo Ave

##### City

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##### Province

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##### Postal code

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##### Phone

+98 13 3333 5820

##### Email

research@gums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Rasht 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

Rasht University of Medical Sciences

##### Full name of responsible person

Seyedeh Fatemeh Dalil Heirati

##### Position

Candidate, MS of midwifery

##### Latest degree

Bachelor

##### Other areas of specialty/work

Midwifery

##### Street address

Al-Zahra Hospital, Namjoo Ave.

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##### Phone

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##### Email

dalilheirati@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Seyedeh Fatemeh Dalil Heirati

##### Position

Candidate, MS of midwifery

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Bachelor

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**Person responsible for updating data****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Seyedeh Fatemeh Dalil Heirati

**Position**

Candidate MS of midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Al-Zahra Hospital, Namjoo Ave.

**City****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**

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**

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**

No - There is not 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