

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Full name of responsible person

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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