

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of vaginal product based on chamomile for treatment of women with dyspareunia

Protocol summary

Summary

Objective: This study aims to assess the effect of a vaginal product made from chamomile for treatment of dyspareunia. **Design:** This study is a single- centered randomized double- blind parallel exploratory trial. 92 women with dyspareunia are divided into two groups: intervention and placebo. Women in intervention group are receiving vaginal product from chamomile and placebo group received the same vaginal product without chamomile. **Setting and conduct:** Patients who meet inclusion criteria participate in this study. At the beginning of the study FSFI and VAS Questionnaires fill up for patients. After 10 days using treatment, patients are followed up for 4 weeks and evaluated with FSFI and VAS questionnaires at the end of study. **Inclusion criteria** are 18- 49 years sexually active women with dyspareunia at least during the 3 last months; having intercourse at least once during a month; having only one sexual partner; having normal gynecological examination; not using oral contraceptives. **Exclusion criteria:** use of hormonal drugs, anti-hypertensive and anti-depressant drugs over a month before beginning of the study; pregnancy; breast-feeding; Menopause. **Interventions:** In intervention group immediately after the end of menstruation, every night before bed for 10 nights, a vaginal tablet of chamomile is placed at the upper end of vagina with applicator. In control group immediately after the end of menstruation, every night before bed for 10 nights, a vaginal tablet of placebo is placed at the upper end of vagina with applicator. **Primary outcome** is pain during intercourse. **Secondary outcomes** are lubrication of vagina, arousal, desire, orgasm and satisfaction during intercourse. **Allocation of study groups** done by random block method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702197511N3**

Registration date: **2017-10-22, 1396/07/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-22, 1396/07/30

Registrant information

Name

Marzieh Qaraaty

Name of organization / entity

Golestan University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 3254 1065

Email address

gharaaty1387@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vaginal product based on chamomile for treatment of women with dyspareunia

Public title

Evaluation of the efficacy of vaginal product based on chamomile for the treatment of dyspareunia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 18 to 49 years old married women with dyspareunia at least during the 3 last months; having intercourse at least once during a month; conscious informed consent; normal gynecological examination; using non-hormonal contraceptives. Exclusion criteria: use of hormonal drugs, anti-hypertensive and anti-depressant drugs over a month before beginning of the study; pregnancy; breast-feeding; Menopause.

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Science, Poursina street, Tehran, Iran

City

Tehran

Postal code**Approval date**

2016-05-24, 1395/03/04

Ethics committee reference number

IR.TUMS.REC.1395.2628

Health conditions studied**1****Description of health condition studied**

Dyspareunia

ICD-10 code

N94.1

ICD-10 code description

Dyspareunia

Primary outcomes**1****Description**

Pain during intercourse

Timepoint

before & after the study

Method of measurement

VAS Questionnaire

Secondary outcomes**1****Description**

Lubrication of vagina during intercourse

Timepoint

before & after the study

Method of measurement

FSFI questionnaire

2**Description**

Arousal during intercourse

Timepoint

before & after the study

Method of measurement

FSFI questionnaire

3**Description**

Desire during intercourse

Timepoint

before & after the study

Method of measurement

FSFI questionnaire

4**Description**

Orgasm during intercourse

Timepoint

before & after the study

Method of measurement

FSFI questionnaire

5

Description

Satisfaction during intercourse

Timepoint

before & after the study

Method of measurement

FSFI questionnaire

Intervention groups

1

Description

Intervention group: Immediately after the end of menstruation, every night before bed for 10 nights, a vaginal tablet of chamomile is placed at the upper end of vagina with applicator

Category

Treatment - Drugs

2

Description

Control group: Immediately after the end of menstruation, every night before bed for 10 nights, a vaginal tablet of placebo is placed at the upper end of vagina with applicator

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Traditional Iranian Medicine,s Clinic of Tehran University

Full name of responsible person

Malihe Tabarraei

Street address

27th number,Traditional Iranian Medicine,s Clinic of Tehran University (Ahmadih), Sarparast street, Taleqani avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Doctor Masoud Yonesian

Street address

Qods street, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Doctor Marzieh Qaraaty

Position

Assistant Professor

Other areas of specialty/work

Street address

7th number, The residential complex of Nikan, 5th Farhang, 9th Sayyad, Martyr Sayyad shirazi,s Boulevard, Gorgan, Iran.

City

Gorgan

Postal code

Phone

+98 17 3254 1065

Fax

+98 17 3254 1065

Email

gharaaty1387@yahoo.com, dr.qaraati@goums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Doctor Malihe Tabarraei

Position

Assistant Professor

Other areas of specialty/work

Street address

27th number, Clinic of Traditional Iranian Medicine of Tehran University of Medical Sciences (Ahmadih), Sarparast street, Taleqani avenue, Tehran, Iran.

City

Tehran

Postal code

Phone

+98 21 8897 6527

Fax

Email

dr.mtabarrai@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Doctor Marzieh Qaraaty

Position

Assistant Professor

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7th number, The residential complex of Nikan, 5th Farhang, 9th Sayyad, Martyr Sayyad shirazi,s Boulevard, Gorgan, Iran.

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Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty