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 fallowed 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 Tabarrai
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 Tabarrai
Position
Assistant Professor
Other areas of specialty/work
Street address
27th number, Clinic of Traditional Iranian Medicine of Tehran University of Medical Sciences (Ahmadieh), 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

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

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