Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Oct 2026

Comparative Study of the effect of CO2 Fractional Laser and Vaginal Cream Premarine on improving sexual function in postmenopausal women

Protocol summary

Study aim

The purpose of this study was to investigate the effect of laser fractional carbon dioxide (CO2) and vaginal cream Premarin on the improvement of sexual function in postmenopausal women.

Design

A two-group clinical trial is in the third phase. Postmenopausal women were selected with the inclusion criteria. Samples were randomly divided into two groups of parallel treatment (n = 25) and control group (n = 25) based on random blocks of size 4 and using sealed envelopes containing cards containing randomized sequences were divided.

Settings and conduct

The present study was a clinical trial of two groups that was performed at the Pelvic Disorders Clinic of Imam Khomeini Hospital affiliated to Tehran University of Medical Sciences. The population under study was the postmenopausal women referring to the clinic.

Participants/Inclusion and exclusion criteria

Postmenopausal women aged 45-65 years, at least one year after of their last menstruation, were entered the study with the sexual activity ،single-sex and monogamy, having dyspareunia and sexual problems associated with vulvovaginal atrophy. Use of any topical or systemic hormone therapy within 6 months before entering the study and use of vaginal lubrication for 30 days before entering the study; Acute or chronic urinary tract infections; Acute Genital Herpes (Herpes Candida); Stage 2 Or more of prolapse, having psychiatric disorders and smoking was a condition for not entering the study.

Intervention groups

Intervention group 1: A group of postmenopausal women treated with co2 laser for three months, once a month. Intervention group 2 (control): A group of postmenopausal women who used the vaginal cream as one-third of the applicator three nights a week.

Main outcome variables

The main outcomes included examining the dimensions of sexual desire, lubrication, orgasm, satisfaction, and disparity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160916029835N3**
Registration date: **2018-10-06, 1397/07/14**
Registration timing: **retrospective**

Last update: **2018-10-06, 1397/07/14**
Update count: **0**

Registration date

2018-10-06, 1397/07/14

Registrant information

Name

tahereh khalili borujeni

Name of organization / entity

tehran university of medical sience

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-08-07, 1396/05/16

Expected recruitment end date

2017-11-07, 1396/08/16

Actual recruitment start date

2017-08-07, 1396/05/16

Actual recruitment end date

2017-11-07, 1396/08/16

Trial completion date

2017-11-07, 1396/08/16

Scientific title

Comparative Study of the effect of CO2 Fractional Laser and Vaginal Cream Premarine on improving sexual function in postmenopausal women

Public title

Comparative Study of the effect of CO2 Fractional Laser and Vaginal Cream Premarine on improving sexual function in Postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having sexual activity Having single sex and monogamy The age range of 65-45 years Having Disparony and Sexual Complications associated with Vaginal Atrophy Women who have passed at least one year of their last menstrual period or women with high FSH 40 The presence of symptoms of vaginal atrophy There is a sexual problem during intercourse Consent to participate in the study

Exclusion criteria:

Use of any type of topical or systemic hormonal alternative therapist for 6 months before entering the study Use of vaginal lubrication within 30 days before entering the study Acute or chronic urinary tract infection Acute Genital Infections (Herpes Candida) Psychiatric disorders interact with the completion of the informed consent form Smoking

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method was a block size of 4, which was a randomized sealed envelope, each of which was randomly recorded on a card, and the cards were inserted into the envelopes respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

6th floor, Ghods St, Keshavarz Blvd.Central Organization of the University, Deputy of Research and Technology of Tehran University of Medical Sciences

City

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Province

Tehran

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Approval date

2017-08-07, 1396/05/16

Ethics committee reference number

IR.TUMS.IKHC.REC.1396.2552

Health conditions studied

1

Description of health condition studied

Sexual dysfunction in postmenopausal women

ICD-10 code

N95.2

ICD-10 code description

Postmenopausal atrophic vaginitis

Primary outcomes

1

Description

Sexual Function

Timepoint

At the beginning of the study and 3 months after the intervention

Method of measurement

Sexual function Questionnaire

Secondary outcomes

1

Description

Improve disparony

Timepoint

At the beginning of the study and 3 months after

treatment

Method of measurement

Questionnaire

2

Description

Improve orgasms

Timepoint

At the beginning of the study and 3 months after treatment

Method of measurement

Questionnaire

3

Description

Improve desire

Timepoint

At the beginning of the study and 3 months after treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Vaginal cream premarine one-third of the oplicator three nights a week for twelve weeks

Category

Treatment - Drugs

2

Description

Vaginal laser co2 monthly for three months

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Tahereh Khalili Borujeni

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Pelvic Clinic,Imam Khoeini Hosital,Keshavarz Boulevard, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Karimi

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Tahereh Khalili Borujeni

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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
There is no program for its release

Study Protocol
No - There is not 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