

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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 science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8889 6696

##### Email address

t-khalilib@razi.tums.ac.ir

##### 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**

Tehran

**Province**

Tehran

**Postal code**

14145

**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

#### Street address

Pelvic Clinic, Imam Khomeini Hospital, Keshavarz Boulevard, Tehran

#### City

Tehran

#### Province

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#### Postal code

14145

#### Phone

+98 21 6119 2271

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khalilitahereh@gmail.com

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

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#### Phone

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drkarimi@tums.ac.ir

#### 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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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