

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Evaluation of efficacy and safety of fractional co2 vs vaginal conjugated estrogen in postmenopausal women diagnosed as having vulvovaginal atrophy

#### Protocol summary

##### Summary

the aim of the study was to assess the safety and efficacy of Fractional co2 VS vaginal conjugated estrogen as a standard treatment of vulvovaginal atrophy in postmenopausal women inclusion criteria: 1. women's between 45-65 age suffering from Amenorrhea since 24 months 2. women's who diagnosed vaginally atrophy in clinical examination 3. women's who have sexual contract exclusion criteria: 1. women who treated with systemic estrogen since 6 months ago 2. history of cancer 3. pathologic change in the cervical Pap smear 4. Renal or liver failure 5. women taking estrogen therapy in past history 6. Radiation therapy of the vagina 7. vulvovaginitis 8. History of psychotropic drug or opium use demographic data including age, education level, Body Mass Index, smoking history, previous live births, sexual activity, the history and duration of previous hormone replacement therapy will be recorded. in this Randomised Clinical Trial, postmenopausal women with vaginal atrophy will be referred to the Emam Khomeini Hospital gynecologic clinic in Ahvaz, assessed by an expert gynecologist. a total of 130 patient will be enrolled in this study and randomly divided into two groups: receiving either " Fractional co2 laser " or "vaginal conjugated estrogen" for the treatment of vulvovaginal atrophy. The vulvovaginal atrophy symptom of patients will be assessed in the first day of treatment and 12 weeks after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017050433817N1**

Registration date: **2017-06-08, 1396/03/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-06-08, 1396/03/18

##### Registrant information

###### Name

saadat Hajatzadeh

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3320 5411

###### Email address

hajatzadeh.s@ajums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Ahvaz Jundishapur University of Medical Sciences

##### Expected recruitment start date

2017-05-22, 1396/03/01

##### Expected recruitment end date

2017-07-23, 1396/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of efficacy and safety of fractional co2 vs vaginal conjugated estrogen in postmenopausal women diagnosed as having vulvovaginal atrophy

##### Public title

Laser vs vaginal conjugated estrogen in postmenopausal

women

## Purpose

Treatment

## Inclusion/Exclusion criteria

(inclusion criteria: women's between 45-65 age suffering from Amenorrhea since 24 months; women's who diagnosed vaginally atrophy in clinical examination; women's who have sexual contract) (exclusion criteria: women who treated with systemic estrogen since 6 months ago; history of cancer; pathologic change in the cervical Pap smear; Renal or liver failure; women taking estrogen therapy in past history; Radiation therapy of the vagina; vulvovaginitis; History of psychotropic drug or opium use)

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **130**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Ahvaz Jundishapur University of Medical Sciences

##### Street address

room 4, Ground Floor, Department of Development Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Ahvaz

##### City

Ahvaz

##### Postal code

1579461357

#### Approval date

2017-05-03, 1396/02/13

#### Ethics committee reference number

IR.ajums.REC.1395.670

## Health conditions studied

### 1

#### Description of health condition studied

vulvovaginal atrophy

#### ICD-10 code

N95.2

#### ICD-10 code description

Postmenopausal atrophic vaginitis

## Primary outcomes

### 1

#### Description

vulvovaginal atrophy symptoms

#### Timepoint

at base line (day 0), 12 weeks post treatment

#### Method of measurement

visual analog scale measurement

## Secondary outcomes

### 1

#### Description

Adverse events

#### Timepoint

at baseline ( day 0), 12 weeks post treatment

#### Method of measurement

according to patient history

### 2

#### Description

Female Sexual Function Index

#### Timepoint

at baseline ( day 0), 12 weeks post treatment

#### Method of measurement

according to Female Sexual Function Index

### 3

#### Description

Sexual satisfaction

#### Timepoint

at baseline ( day 0), 12 weeks post treatment

#### Method of measurement

visual analog scale measurement

## Intervention groups

### 1

#### Description

The Fractional CO2 laser with Angela trademark( Fractional CO2 LASER MX-7000 smart pulse) , the treatment will be used for 3 Sessions and 4 weeks intervals

#### Category

Treatment - Other

## 2

### Description

topical conjugated estrogen (0.625 mg conjugated equine estrogens per 1 g vaginal cream; n = 30) administered once daily for two weeks, then twice weekly for 8 weeks.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital Ahvaz Urogynecology Clinic

##### Full name of responsible person

Hajatzadeh Saadat

##### Street address

Imam Khomeini Hospital Clinic, 24 metery Avenue,  
Ahvaz

##### City

Ahvaz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences,  
Research Development Unit0

##### Full name of responsible person

Mohammad Dianat

##### Street address

room 4, Ground Floor, Department of Development  
Research and Technology, Ahvaz Jundishapur  
University of Medical Sciences, Ahvaz

##### City

Ahvaz

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Ahvaz Jundishapur University of Medical Sciences,  
Research Development Unit0

##### 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

Ahvaz Jundishapur University of Medical Sciences

#### Full name of responsible person

Hajatzadeh Saadat

#### Position

Resident of Obstetrics and Gynecology

#### Other areas of specialty/work

#### Street address

Ahvaz Jundishapur University of Medical Sciences,  
Golestan Boulevard. Postal code:61357-15794 ,post  
box:159

#### City

Ahvaz

#### Postal code

1579461357

#### Phone

+98 61 3161

#### Fax

#### Email

info@ajums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

#### Full name of responsible person

Hajatzadeh Saadat

#### Position

Resident of Obstetrics and Gynecology

#### Other areas of specialty/work

#### Street address

Golestan Boulevard,Ahvaz Jundishapur University of  
Medical Sciences,Postal code:61357-15794 ,post  
box:159

#### City

Ahvaz

#### Postal code

#### Phone

+98 61 3161

#### Fax

#### Email

info@ajums.ac.ir

#### Web page address

http://ajums.ac.ir/

## Person responsible for updating data

### Contact

#### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

#### Full name of responsible person

Hajatzadeh Saadat

#### Position

Resident of Obstetrics and Gynecology

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Ahvaz

**Postal code**

**Phone**

00

**Fax**

**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*