

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

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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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty