Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 2026

Application of CO2 Fractional Laser to Improve the Symptoms of Vulvovaginal and Prolapse Atrophy in Postmenopausal Women Referring to Yas Hospital,97-98

Protocol summary

Study aim
The effect of fractional laser on vaginal dryness in postmenopausal women The effect of Fractional Laser on Urinary Symptoms in Postmenopausal Women The effect of fractional laser on the quality of sexual life of postmenopausal women The effect of fractional laser on the quality of life of postmenopausal women

Design
The fractional microablative CO2 laser system (SmartXide 2 V 2 LR, Monalisa Touch, DEKA, Florence, Italy) was applied. Laser energy was transmitted through a vaginal probe, the fractional density of 4% to 5%, and an energy level of 50 to 60 mJ. The headpiece was inserted into the vaginal canal (up to 12 cm). In order to provide a complete treatment of the vaginal wall, vaginal probe was rotated 360 °along the vaginal canal. The laser was projected towards a 45 ° oriented mirror placed at the tip of the probe so that it was only reflected on the vaginal walls but not on the uterine cervix. Data Collection with standard questionnaire collected in the first and 4 weeks after last visit.

Settings and conduct
Using the fractional Laser Device in Yas Hospital

Participants/Inclusion and exclusion criteria
A postmenopausal woman aged 45 to 65 years with symptoms of vaginal atrophy that lasts more than 24 months after menopause. The criteria for entering the study include: Vaginal dryness, irritation, pruritus, urinary symptoms and painful intercourse Exit criteria: • Hormone therapy (topical or systemic) in the last 12 months • Use of vaginal moisturizers and gels • Genitourinary infection (Vulvovaginitis) • Women who use psychotropic drugs • BMI higher than 35 • Current cancer history • Abnormal Pap smear • Menopause induced by medication • History of steroid use • History of vaginal radiotherapy in the past

Intervention groups
non

Main outcome variables
change in quality of life based on the completion of the questionnaire before and after the exposure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180409039247N2**
Registration date: **2019-06-10, 1398/03/20**
Registration timing: **retrospective**

Last update: **2019-06-10, 1398/03/20**
Update count: **0**

Registration date
2019-06-10, 1398/03/20

Registrant information

Name
Marjan Ghaemibidgoli

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Application of CO2 Fractional Laser to Improve the Symptoms of Vulvovaginal and Prolapse Atrophy in Postmenopausal Women Referring to Yas Hospital,97-98

Public title
Application of CO2 Fractional Laser to Improve the Symptoms of Vulvovaginal and Prolapse Atrophy in Postmenopausal Women Referring to Yas Hospital

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
postmenopausal woman aged 45 to 65 years with symptoms of vaginal atrophy that lasts more than 24 months after menopause. Vaginal dryness, irritation, pruritus, urinary symptoms and painful intercourse
Exclusion criteria:
Hormone therapy (topical or systemic) in the last 12 months• Use of vaginal moisturizers and gels• Genitourinary infection (Vulvovaginitis)• Women who use psychotropic drugs• BMI higher than 35• Current cancer history• Abnormal Pap smear• Menopause induced by medication• History of steroid use• History of vaginal radiotherapy in the past

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: **100**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran university of Medical sciences

Street address
TUMS, Poorsina street, Ghods avenue, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
123456

Approval date
2019-04-04, 1398/01/15

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.010

Health conditions studied

1

Description of health condition studied
Vaginal dryness, irritation, pruritus, urinary symptoms and painful intercourse

ICD-10 code
THEY ARE S

ICD-10 code description
THEY ARE SYMPTOMS

Primary outcomes

1

Description
We expect the quality of life that measure with standard devices (The questionnaire of quality of life questionnaire (SF-12), the Incontinence Questionnaire-Short Form (ICIQ-SF), the Female Sex Function Index6- The Menopause-Specific Quality of Life) will change in our study

Timepoint
At the beginning of the study and 4 weeks after the last treatment

Method of measurement
standard questionnaire that are validated in Iran

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The fractional microablative CO2 laser system (SmartXide 2 V 2 LR, Monalisa Touch, DEKA, Florence, Italy) was applied. Laser energy was transmitted through a vaginal probe, the fractional density of 4% to 5%, and an energy level of 50 to 60 mJ. The headpiece was inserted into the vaginal canal (up to 12 cm). In order to provide a complete treatment of the vaginal wall, vaginal probe was rotated 360 °along the vaginal canal. The laser was projected towards a 45 °

oriented mirror placed at the tip of the probe so that it was only reflected on the vaginal walls but not on the uterine cervix.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Yas hospital

Full name of responsible person
Marjan Ghaemi

Street address
Yas hospital, North villa street, Karimkhan zand avenue, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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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
Marjan Ghaemi

Position
OB-GYN Resident

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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resident

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Person responsible for updating data

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Latest degree
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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
Principles of confidentiality and non-disclosure of the identity of the participants

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available