

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Assessment of fractional co2 laser effect in treatment of women with vulvovaginal atrophy in Emam Khomeini hospital

Protocol summary

Study aim

Investigating the Effect of Fractional CO2 Therapy on the Improvement of Vaginal Atrophy Symptoms

Design

In a study of 35 patients with vaginal atrophy and having a condition to study at the Pleivc Clinic of Women referring to Imam Khomeini Hospital, all participants are treated as a group.

Settings and conduct

Patients referred to vaginal atrophy symptoms in Vali-e-Asr Hospital in Pleivc Clinic And eligible for inclusion in the study after being informed consent. Signs and severity are collected by the questionnaire form at the beginning of the study. Three sessions of laser therapy are then performed at a distance of one month Symptoms are re-evaluated at each session and end. Patients after the completion of three sessions, up to one year of the Follow up

Participants/Inclusion and exclusion criteria

Criteria for entering the study : The age of the patient is over 45 years old. There is no history of surgery in the perineal area. There is no history of using hormone therapy. Complaint Disparonya patient with or without symptoms of urinary incontinence. There is no history of neuropathy or mental illness. Non-admission criteria : Age of the patient under 45 years of age. History of Perineal Surgery. A history of neuropathy or mental illness. The history of hermeneutic therapy. No complaints of dyspareunia or urinary disorders.

Intervention groups

Female patients older than 45 years of age with a complaint of Disparonya and urinary incontinence symptoms referred to Pleivc Clinic of Imam Khomeini Hospital and undergoing laser therapy are three sessions.

Main outcome variables

Dry vagina : Vaginal itching : Vaginal discharge : Disparonya : Dysuria : Urinary incontinence .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171004036562N2**

Registration date: **2020-06-11, 1399/03/22**

Registration timing: **retrospective**

Last update: **2020-06-11, 1399/03/22**

Update count: **0**

Registration date

2020-06-11, 1399/03/22

Registrant information

Name

safa Alasiri

Name of organization / entity

Tehran Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

s-sohbat@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of fractional co2 laser effect in treatment of women with vulvovaginal atrophy in Emam Khomeini hospital

Public title

Assessment of laser effect in treatment of women with vulvovaginal atrophy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

one or more symptoms of VVA (e.g., vaginal discharge, itching, dyspareunia, dryness and urge urinary incontinence). no menstruation for ≥ 12 months. not using local or systemic estrogen therapy. wishing to be sexual active.

Exclusion criteria:

: use of hormone replacement therapy (systemic or local) up to 6 month before entry to the study. pelvic organ prolapse stage > 2 (according to POP-Q system). active genital infections. acute or recurrent urinary tract infection. use of any vaginal lubricants. moisturizers or local preparations within 30 days before entry to the study. psychiatric disorders which could interfere with informed consent. any chronic disease that could interfere with study compliance. abnormal uterine bleeding which has no exact diagnosis. malignancies of urogenital.

Age

From **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **35**

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

Ethics Committee of Tehran University of Medical

Sciences

Street address

Quds St., Poursina St., Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

123456

Approval date

2017-06-09, 1396/03/19

Ethics committee reference number

IR.TUMS.IKHC.REC.1396.2552

Health conditions studied

1

Description of health condition studied

Atrophy of the vagina

ICD-10 code

N95.2

ICD-10 code description

Postmenopausal atrophic vaginitis

Primary outcomes

1

Description

The percentage of women who have vaginal dryness.

Timepoint

The time intervals for assessing the vaginal dryness before the start of the laser and then one month two months and three months and one year after the laser is done.

Method of measurement

questionnaire

2

Description

Percentage of women who have urinary incontinence.

Timepoint

The time intervals for assessing the vaginal dryness before the start of the laser and then one month two months and three months and one year after the laser is done.

Method of measurement

questionnaire

Secondary outcomes

1

Description

Dysuria together

Timepoint

The time intervals for assessing the vaginal dryness before the start of the laser and then one month two months and three months and one year after the laser is

done.
Method of measurement
questionnaire

2

Description

Vaginal itching accompanied.

Timepoint

The time intervals for assessing the vaginal dryness before the start of the laser and then one month two months and three months and one year after the laser is done.

Method of measurement
questionnaire

3

Description

Vaginal discharge accompanied.

Timepoint

The time intervals for assessing the vaginal dryness before the start of the laser and then one month two months and three months and one year after the laser is done.

Method of measurement
questionnaire.

4

Description

Dyspareunia.

Timepoint

The time intervals for assessing the vaginal dryness before the start of the laser and then one month two months and three months and one year after the laser is done.

Method of measurement
questionnaire

Intervention groups

1

Description

Intervention group: The intervention group uses fractional carbon dioxide laser, which is used in 3 sessions and 4 weeks apart.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-e-Asr Hospital - Imam Khomeini Hospital Complex

Full name of responsible person

Safa Al-Asiri

Street address

IRAN - Tehran-Chamran Highway. Baqer Khan Street.

Imam Khomeini Hospital Complex. Vali Asr Hospital
City
TEHRAN
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Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6658 1420
Email
Imamhospital@tums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Zinat Ghanbari

Street address

Quds St., Poursinao St., Tehran University of Medical Sciences

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1417653761

Phone

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info@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

Dr. Safa Al-Asiri

Position

Residency in Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Tehran - Tehransar - Laleh Blvd. - North Badakhshan
St. - Shahid Hasheminejad Town - Block D6 Unit 16

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Safa Al-Asiri

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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

Principles of confidentiality and non-disclosure of participants' identities

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