

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of radiofrequency and laser treatment on symptoms of Iranian menopausal women with mixed urinary incontinence and vulvovaginal atrophy

Protocol summary

Study aim

Comparison the effect of radiofrequency and laser treatment on mixed urinary incontinence (UI) and vulvovaginal atrophy (VVA) in Iranian menopausal women

Design

A randomized controlled clinical trial with two intervention and one control group, consisted of 240 patients, 80 patients in each group.

Settings and conduct

After definite diagnosis of UI and VVA and randomized allocation of patients to each group, the RF and laser treatments will be performed in the treatment groups while patients in the control group only received placebo treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: history of UI symptoms; having sexual intercourse; having sexual problems due to VVA; at least one year after the termination of menstruation; presence of VVA symptoms; sexual dysfunction. Non-inclusion criteria: patients with urinary infection; hematuria; pelvic organ prolapse ICS>2; abnormal vaginal bleeding; radical hysterectomy with noropathy; leakage of urine more than 50 g per hour

Intervention groups

Intervention group 1: laser treatment. Intervention group 2: RF treatment. Control groups: placebo treatment.

Main outcome variables

Urinary incontinence; Vulvovaginal atrophy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190708044143N1**

Registration date: **2019-09-01, 1398/06/10**

Registration timing: **retrospective**

Last update: **2019-09-01, 1398/06/10**

Update count: **0**

Registration date

2019-09-01, 1398/06/10

Registrant information

Name

Farima Mohamadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2019-06-21, 1398/03/31

Trial completion date

2019-06-21, 1398/03/31

Scientific title

Comparison the effect of radiofrequency and laser treatment on symptoms of Iranian menopausal women with mixed urinary incontinence and vulvovaginal atrophy

Public title

Comparison the effect of radiofrequency and laser treatment on mixed urinary incontinence and vulvovaginal atrophy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

history of UI symptoms having sexual intercourse having sexual problems due to vulvovaginal atrophy (VVA) at least one year past from the termination of menstruation presence of VVA symptoms sexual dysfunction

Exclusion criteria:

urinary infection hematuria pelvic organ prolapse ICS>2 pregnancy childbirth in less than a year abnormal vaginal bleeding damaged vaginal tissue history of damage to spinal nerves radical hysterectomy with noropathy epilepsy autoimmune diseases leakage of urine more than 50 g per hour

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **240**

Actual sample size reached: **246**

Randomization (investigator's opinion)

Randomized

Randomization description

According to random numbers table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

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

No.78, Moosivand avenue, Shariati street

City

Tehran

Province

Tehran

Postal code

1933983911

Approval date

2019-05-01, 1398/02/11

Ethics committee reference number

IR.TUMS.IKHC.REC.1398.035

Health conditions studied

1

Description of health condition studied

Mixed Urinary Incontinence

ICD-10 code

N39.4

ICD-10 code description

Other specified urinary incontinence

Primary outcomes

1

Description

Urinary incontinence includes the frequency of urinary leakage, urine leakage, the effect of urine leakage on quality of life and urinary leakage time.

Timepoint

pre and post of intervention

Method of measurement

ICIQ-SF questionnaire

2

Description

Vaginal atrophy including burning, itching, dryness, dispersion and dysuria

Timepoint

pre and post of intervention

Method of measurement

Visual analog score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: Laser treatment will consist of a series of 2 treatments, 4 weeks apart, taking about 1-2 min per session, as an in-office procedure using Monalisa Touch device aimed at treatment of VVA, UI, and sexual problems.

Category

Treatment - Other

2

Description

Intervention group 2: In RF therapy group, all patients have 3 sessions of treatment, with 4-6 weeks frequency. Each session will be held in groups for 30 minutes with a

working temperature range of 40–45°C.

Category

Treatment - Other

3

Description

Control group: no treatment

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of pelvic floor of Valiasr Hospital in Tehran

Full name of responsible person

Fatemeh Dolatshad

Street address

After Mirdamad, Valiasr street

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Tehran

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1996714184

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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?

No

Title of funding source

Vic-Chancellor in Research of 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

Laila Ghorbani

Position

gynecologist

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Laila Ghorbani

Position

gynecologist

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farima Mohamadi

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

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