

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Investigation of the effect of radiofrequency on improvement of vaginal laxity and loss of sexuality in women referring to Mashhad educational hospital clinics

Protocol summary

Study aim

Determining the effect of radiofrequency on improving vaginal laxity and reduced sexual desire in women referring to the Mashhad educational hospital clinics

Design

Clinical trial with no control or parallel groups, not blinded and not randomized, and conducted on 30 patients

Settings and conduct

This study will be performed on 30 women referring to the hospital clinic with complaints of vaginal laxity. A gynecology resident performs vaginal examination on patients and based on inclusion criteria, patients enter the study. The treatment is ambulatory and is conducted in a clinic. Patients are treated with a radiofrequency device in three sessions and each session lasts 30 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 25-50 years; having complaints of vaginal laxity; not having breastfed within the the three months before the study; sexual activity; normal Pap test result; negative pregnancy test before entering the study. Exclusion criteria: pelvic organ prolapse has exceeded the hymenal ring; active sexually transmitted disease; chronic vulvar pain or vulvar dystrophy; using known medications that affect sexual function; daily use of anti-inflammatory drugs which can affect collagen in healing; chronic skin disorder including vulvar involvement; medical problem that interferes with wound healing; thin rectovaginal septum; being under treatment for hypoactive sexual dysfunction (HSDD) or orgasmic disorder; detected IBS

Intervention groups

Patients are treated with a radiofrequency device in three sessions and each session lasts 30 minutes within 1 to 3 months. This thermotherapy device uses radiofrequency technology to treat vaginal laxity and

rejuvenate the external genitalia in women.

Main outcome variables

Sexual function, vaginal laxity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201006048949N1**

Registration date: **2021-08-10, 1400/05/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-10, 1400/05/19**

Update count: **0**

Registration date

2021-08-10, 1400/05/19

Registrant information

Name

Azimeh Golzar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3727 9757

Email address

golzarta961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-28, 1400/05/06

Expected recruitment end date

2022-02-25, 1400/12/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of radiofrequency on improvement of vaginal laxity and loss of sexuality in women referring to Mashhad educational hospital clinics

Public title

The effect of radiofrequency on improvement of vaginal laxity and loss of sexuality in women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 25-50 years Having complaints of vaginal laxity Not having breastfed within the the three months before the study Sexual activity (vaginal sex at least once a month) Normal Pap test result Negative pregnancy test before entering the study

Exclusion criteria:

Pelvic organ prolapse has exceeded the hymenal ring (grade 3 and 4 prolapse) Active sexually transmitted disease (Condylomata acuminata / herpes) Chronic vulvar pain or vulvar dystrophy Using known medications that affect sexual function (antihypertensive and psychotropic drugs / chemotherapeutic agents) Daily use of anti-inflammatory drugs which can affect collagen in healing (ibuprofen / aspirin / steroids) Chronic skin disorder including vulvar involvement Medical problem that interferes with wound healing. Thin rectovaginal septum Under treatment for Hypoactive Sexual Desire Disorder (HSDD) or orgasmic disorder Irritable bowel syndrome (IBS)

Age

From **25 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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 Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2020-09-26, 1399/07/05

Ethics committee reference number

IR.MUMS.REC.1399.458

Health conditions studied**1****Description of health condition studied**

Vaginal laxity

ICD-10 code

N81

ICD-10 code description

Female genital prolapse

Primary outcomes**1****Description**

Sexual function

Timepoint

Before the intervention, at months 1, 2, 3 during the study before each treatment session, and 3and 6 months after the intervention

Method of measurement

Female Sexual Function Index

2**Description**

Vaginal laxity

Timepoint

Before the intervention, at months 1, 2, 3 during the study before each treatment session, and 3and 6 months after the intervention

Method of measurement

Vaginal Laxity Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, treatment was ambulatory and was done in a clinic. Patients are treated with a radiofrequency device in three sessions and each session lasts 30 minutes within 1 to 3 months. This thermotherapy device uses radiofrequency technology to treat vaginal laxity and rejuvenate the external genitalia in women. This device can work with four different frequencies (420,500,720,1000), which allows changing the depth of penetration of the waves according to the type of patient's problem and the type of treatment needed.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad educational hospital clinics

Full name of responsible person

Nafiseh Saghafi

Street address

Ahmadabad St., Ghaem Hospital

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99199-91766

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Azimeh Golzar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nafiseh Saghafi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact
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Mashhad University of Medical Sciences
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Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data can be accessible through an email to the corresponding author.

Under which criteria data/document could be used

Data will be available for researchers in universities and other scientific institutes.

From where data/document is obtainable

After sending a request email to the corresponding author, data will be sent in 1 month.

What processes are involved for a request to access data/document

Carrying out analysis on data is permitted.

Comments