Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of the effect of radiofrequency on improvement of vaginalaxity 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)

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+98 51 3727 9757

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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 vaginalaxity and loss of sexuality in women referring to Mashhad educational hospital clinics

Public title
The effect of radiofrequency on improvement of vaginalaxity 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
Vaginalaxity
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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad 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
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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NO. 31, Haft Tir 3 St., Vakilabad Blvd.,

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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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Associate professor
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Gynecology and Obstetrics
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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