Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Radiofrequency Therapy Effectiveness on Sexual Dysfunction in Female Cancer Survivors (Gynecologic & Breast) Compared to Non-cancer Menopause Subjects

Protocol summary

Study aim
Evaluation of radiofrequency therapy effectiveness on sexual dysfunction in female cancer survivors compared to non-cancer subjects

Design
A clinical trial that the same intervention will be given to 74 patients and non-patients.

Settings and conduct
Patients with gynecological cancers (cervix, uterus, vulva, vagina, ovary), breast cancer and the second group including non-cancerous postmenopausal patients referred to the clinic of Imam Hossein Hospital who also complained of sexual dysfunction.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Menopausal women with sexual activity, those with malignancy after 3 months of treatment Exclusion criteria: Hormone therapy (systemic or local) or other treatments for sexual dysfunction including moisturizers, women with mild sexual function problems, patients with active or recurrent genital tract infection, patients with HIV, urinary tract infection , pelvic reconstructive surgery, having a cardiac pacemaker, having an intrauterine device, pregnancy, breastfeeding, skin disease and not signing the consent form

Intervention groups
Patients refer three times with an interval of one month. The plate will be placed under the patient's buttocks. It works on the external genitalia for 10 minutes using an external prop with a frequency of KHZ720 and on the monopolar mode. After that, it will be worked by an internal prop with a frequency of KHZ720 and on bipolar mode for 10 minutes inside the vaginal canal.

Main outcome variables
Dyspareunia; Sexual desire; Sexual arousal; Sexual satisfaction; Sexual lubrication; Orgasm

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160531028187N2**
Registration date: **2022-11-19, 1401/08/28**
Registration timing: **prospective**

Last update: **2022-11-19, 1401/08/28**
Update count: **0**

Registration date
2022-11-19, 1401/08/28

Registrant information

Name
Mahshid Vasef

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7343 3000

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Radiofrequency Therapy Effectiveness on Sexual Dysfunction in Female Cancer Survivors (Gynecologic & Breast) Compared to Non-cancer Menopause Subjects

Public title
Evaluation of radiofrequency therapy effectiveness on sexual dysfunction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Sexually active postmenopausal women Patients with malignancy 3 months after completing treatment
Exclusion criteria:
Hormone therapy (systemic or topical) or other treatments for sexual dysfunction (such as moisturizers) Mild sexual dysfunction (score above 28 according to the questionnaire) Patients with active or recurrent genital tract infection (such as herpes or candida infection) People infected with HIV Urinary tract infection Pelvic reconstructive surgery Having a pacemaker Having intra-uterine device Pregnancy Breast feeding Skin diseases Not signing the informed consent form
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Imam Hossein Hospital., Shahid Madani Ave., Tehran
City
Tehran
Province
Tehran
Postal code
1617763141
Approval date
2022-10-22, 1401/07/30
Ethics committee reference number
1401.489.IR.SBMU.RETECH.REC

Health conditions studied

1

Description of health condition studied
Sexual dysfunction
ICD-10 code
R37
ICD-10 code description
Sexual dysfunction, unspecified

Primary outcomes

1

Description
Dyspareunia
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Female Sexual Function Index Scoring questionnaire

2

Description
Sexual Desire
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Female Sexual Function Index Scoring questionnaire

3

Description
Sexual Arousal
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Female Sexual Function Index Scoring questionnaire

4

Description
Sexual Satisfaction
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Female Sexual Function Index Scoring questionnaire

5

Description
Sexual Lubrication
Timepoint
Before the intervention and three months after the Intervention
Method of measurement
Female Sexual Function Index Scoring questionnaire

6

Description
Orgasm
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Female Sexual Function Index Scoring questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patient with cancer refers three times with an interval of one month. The plate is placed under the patient's buttocks. It works on the external genitalia for 10 minutes using an external prop with a frequency of KHZ720 and on the monopolar mode. After that, it is worked using an internal prop with a frequency of KHZ720 and on bipolar mode for 10 minutes inside the vaginal canal.
Category
Treatment - Devices

2

Description
Intervention group 2: Non-cancer patient refers three times with an interval of one month. The plate is placed under the patient's buttocks. It works on the external genitalia for 10 minutes using an external prop with a frequency of KHZ720 and on the monopolar mode. After that, it is worked using an internal prop with a frequency of KHZ720 and on bipolar mode for 10 minutes inside the vaginal canal.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Malihe Arab
Street address
Imam Hossein Hospital., Shahid Madani Ave., Tehran
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Web page address
https://www.ehmc.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Imam Hossein Hospital., Shahid Madani Ave., Tehran
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahshid Vasef
Position
Fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Web page address
https://www.ehmc.ir/

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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not 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
In this study, only part of the information related to the main outcome can be shared.
When the data will become available and for how long
The access period starts 6 months after the results are published.
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Analyzes aimed at scientific progress and treatment improvement.
From where data/document is obtainable
Apply via email or visit the archive department of Imam Hossein hospital.

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

If requested by email, the data will be emailed within a week.

Comments