

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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)

Phone

+98 21 7343 3000

Email address

vasef@sbmu.ac.ir

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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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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Email

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Web page address

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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 scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Malihe Arab

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

Fellowship

Latest degree

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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

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