Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of two intervention methods (pelvic floor exercise and moisturizing cream) on sexual function and disparity in women undergoing systemic cancer

Protocol summary

Study aim
Determining the effect of two interventions (pelvic floor exercise and moisturizing cream) on sexual function and dyspareunia in women with systemic cancer

Design
90 patients with systemic cancer have 30 patients in each of the three groups This study is a double-blind study

Settings and conduct
Iran Mehr Health Center in Birjand

Participants/Inclusion and exclusion criteria
1. The informed consent of the patient and his wife to enter the study 2-Patients aged 20 to 50 years. 3. Cancer that is systemically treated. 4. Sexual dysfunction, which is specified in the FSFI questionnaire with a score below 25. 5. Do not take medication to help improve sexual dysfunction and vaginal dryness if you take these medications before interrupting your medication. 6. Non-incontinence of urine and stool and kidney and bladder cancer 7. Not having a catration history in the last two months 8. Not being treated for mental disorders (depression and anxiety). 9-Urethrocole, Rectosyl and Cystocel grid 3 and above

Intervention groups
Pelvic floor exercise group control group Moisturizing cream group

Main outcome variables
Sexual Function, Dispensary, Moisturizing Cream, Pelvic Floor Exercise

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190619043952N1**
Registration date: **2019-08-20, 1398/05/29**
Registration timing: **retrospective**

Last update: **2019-08-20, 1398/05/29**
Update count: **0**

Registration date
2019-08-20, 1398/05/29

Registrant information

Name
saeedeh irandoost

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-05, 1398/05/14

Expected recruitment end date
2019-08-16, 1398/05/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of two intervention methods (pelvic floor exercise and moisturizing cream) on sexual function and disparity in women undergoing systemic cancer

Public title

Comparison of the effect of two intervention methods (pelvic floor exercise and moisturizing cream) on sexual function and disparity in women undergoing systemic cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. The informed consent of the patient and his wife to enter the study2-Patients aged 20 to 50 years.3. Cancer that is systemically treated.4. Sexual dysfunction, which is specified in the FSFI questionnaire with a score below 25.5. Do not take medication to help improve sexual dysfunction and vaginal dryness if you take these medications before interrupting your medication.6. Non-incontinence of urine and stool and kidney and bladder cancer7. Not having a catration history in the last two months8. Not being treated for mental disorders (depression and anxiety).9-Urethrocole, Rectosyl and Cystocel grid 3 and above.10-Absence of vaginal infection and urinary tract infection11-Incidence of pelvic fracture12. Do not be breastfeeding

Exclusion criteria:

1-Patient dissatisfaction with the continuation of the intervention2. Cancer recurrence and lack of response to treatment3-pregnancy

Age

From **25 years** old to **55 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

More than 1 sample in each individual

Number of samples in each individual: **30**

We will select 90 patients with systemic cancer and then randomly place 30 people in each of the three control groups, moisturizing cream and pelvic floor exercises.

Randomization (investigator's opinion)

Randomized

Randomization description

After referring to Birjand Iran Mehr Medical Center in Iran and completing the questionnaire regarding gender, vocabulary monitoring, selection and gender questionnaire. Anyone who is under 25 is eligible for the daily questionnaire and can be arranged. Martian dyspareunia may contact you within two months, we can use these specialists with financial services. Genital, urethral, rectocele, systocele (grade 3) have been rejected. The Oxford Fingerprint Limit can be completed by you. If you want to be asked to serve as a Guidance Manager in three 30-person groups. Considering the type of cancer and age,Simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients participating in other groups are unaware A gynecologist who performs gynecological examinations is unaware of the type of intervention performed for each patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IR.BUMS.REC.1397.159

Street address

Birjand University of Medical Sciences, Birjand, Iran

City

bhrjand

Province

South Khorasan

Postal code

۹۷۱۷۸۵۳۵۷۷

Approval date

2018-09-24, 1397/07/02

Ethics committee reference number

IR.BUMS.REC.1397.159

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

sexual dysfunction

Timepoint

Sexual function measurement one month after the intervention, two months after the intervention and two months after the end of the intervention

Method of measurement

Sexual Function Questionnaire of Rosen Women, Marinop's Scale, Linear Pain Scale, Oxford Scale

Secondary outcomes

1

Description
Pelvic floor exercise, moisturizing cream
Timepoint
Sexual function measurement one month after the intervention, two months after the intervention, and finally two months after the end of the intervention.
Method of measurement
Rosen Sex Function Questionnaire, Linear Pain Tool, Marinop Scale, Oxford Scale

2

Description
Dyspuronia
Timepoint
Sexual function measurement one month after the intervention, two months after the intervention, and finally two months after the end of the intervention.
Method of measurement
Rosen Sex Function Questionnaire, Linear Pain Tool, Marinop Scale, Oxford Scale

Intervention groups

1

Description
Intervention group: Intervention group: First, Marin.F and Oxford Sexual Performance Inventory and a linear pain relief tool for one month. The moisturizing cream and the second one are performed for one month of pelvic floor exercise. Then the questionnaire is completed. In the second month of the intervention, it is repeated for the load The second questionnaire will be completed and two months will be considered a faloo-up and completed for the fourth time of the questionnaires.And compared to the control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran health center in Birjand
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
Birjand 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
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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Questionnaires, statistical information
When the data will become available and for how long
After finishing the research work
To whom data/document is available
University of Medical Sciences
Under which criteria data/document could be used
At the request of the relevant organization
From where data/document is obtainable
Ahmad Nasiri
What processes are involved for a request to access data/document
At the written request of the research vice president
Comments