Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of provision of information on anxiety before surgery in patients with breast cancer

Protocol summary

Study aim
Determining the preoperative awareness of anxiety in patients undergoing breast cancer surgery

Design
Clinical trial has two groups of control and intervention with parallel groups that have been randomized without blindness. The clinical trial has two groups of control and intervention with parallel groups that have been randomized without blindness.

Settings and conduct
The research environment is the Department of Women's Surgery and Institute for Disease Control, affiliated to Imam Khomeini Hospital, affiliated to Tehran University of Medical Sciences. Sampling in this research is done randomly and using quadrilateral blocks method.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 before menopause Definitive diagnosis of breast cancer The first surgical experience Ability to read and write Fluency in Farsi Lack of family relationship with other participants in the research Not having a cancer patient in the family Not to be a medical staff Lack of speech and hearing problems Lack of dementia and cognitive impairment The hospital stay is at least 24 hours Not receiving drugs that can reduce or increase cortisol (such as corticosteroids, anticonvulsants, insulin) One-way mastectomy candidate Exit criteria: Any severe changes and deterioration in the condition during the study Any type of offensive treatment during the study Any patient dissatisfaction during the implementation of the project

Intervention groups
The intervention and control group includes all clients aged 18 before menopause with a definitive diagnosis of breast cancer who have been admitted for at least 24 hours for unilateral mastectomy in the Cancer Institute's Cancer Institute

Main outcome variables
Salivary cortisol; anxiety

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181130041803N1**
Registration date: **2018-12-03, 1397/09/12**
Registration timing: **prospective**

Last update: **2018-12-03, 1397/09/12**
Update count: **0**

Registration date
2018-12-03, 1397/09/12

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-01-05, 1397/10/15
Expected recruitment end date
2019-03-11, 1397/12/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of provision of information on anxiety before surgery in patients with breast cancer

Public title
The effect of provision of information on anxiety before surgery in patients with breast cancer

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
The first surgical experience Ability to read and write Mastering in Persian language There is no familial relationship with other participants in the research There is no cancer in the family Not to be a medical staff Do not have a speech and hearing problem Dementia and cognitive impairment At least 24 hours in hospital No medications that reduce or increase cortisol (such as corticosteroids, anticonvulsants, insulin) One-way mastectomy candidate is a one-way mastectomy candidate Definitive diagnosis of breast cancer

Exclusion criteria:
Any severe changes and deterioration in the condition during the study Any type of offensive treatment during the study Any patient dissatisfaction during the implementation of the project

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**
More than 1 sample in each individual
Number of samples in each individual: **2**
Saliva Sample To Check Salvia Cortisol

Randomization (investigator's opinion)
Randomized

Randomization description
Random Rearranged Block Designs Two Blind Quadruple Treatments: Thus, the letter A for the intervention group and the letter B for the control group are considered. Then we write all the reciprocal combinations of the letters A, A, B and B, which are 6 different combinations, on the 6 cards, thus: 1. AABB 2. ABBA 3. ABAB 4. BAAB 5. BABA 6. BBAA Then we select random numbers from digits 1 through 6 (by random number table or patient number one we want to randomly select a card). For example, if the number 2 is selected, the concept is that the first person in the intervention group was the next two in the control group and the fourth in the intervention group, and we continue to do this until the sample size reaches the quotient

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
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Tehran University of Medical Sciences.,Dr Mirkhani St. (Eastern Nusrat).,Tohid Square

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Approval date
2018-11-06, 1397/08/15

Ethics committee reference number
IR.TUMS.FNM.REC.1397.144

Health conditions studied

1

Description of health condition studied
Breast Cancer

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Salivary cortisol

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Anxiety before surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Measuring the salivary cortisol

Timepoint
۶۷/۵۰۰Measure salivary cortisol before the intervention and the morning after the intervention

Method of measurement
Salivary Cortisol Measurement by ELISA Method by Measuring Saline Cortisol Kit

2

Description
Psychological anxiety score of patients with mastectomy candidates in DASS-21 questionnaire

Timepoint
Measurement of anxiety at the beginning of the study and the day after the interventionپرسشنامه

Method of measurement
Anxiety and Stress Questionnaire DASS-21

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group included all patients aged 18 years before menopause with definite diagnosis of breast cancer who were admitted for unilateral mastectomy for at least 24 hours in the Department of Women's Surgery or Immunomotor Cancer Institute who were randomly assigned to blocks Four have been selected in this group after collecting information about demographic and salivary samples from 3 to 5 cc before being informed. Saliva samples are taken to measure cortisol concentrations between 8:30 and 7:30 in the morning. Brushing and eating and drinking is not allowed for the client for half an hour before taking saliva. Samples are immediately sent to the laboratory and freeze at -20 ° F. Then it is centrifuged at 2500 rpm and ultimately measured by ELISA and using the kit of salivary cortisol. Then, the DASS-21 anxiety inventory questionnaire will be completed by patients with the presence of the researcher. To the intervention group, in order to inform and inform before surgery, the written information includes information on patient health and surgical care and post-operative care, and oral explanations and responses to the questions of the patients are also done by the researcher. The saliva sample is collected again and the DASS-21 questionnaire is completed

Category
N/A

2

Description
Control group: Patients in the control group included all patients aged 18 before menopause with a diagnosis of breast cancer who were admitted for unilateral mastectomy for at least 24 hours in the gynecologic department of Imam Khomeini Cancer Institute who were randomly assigned to blocks Four have been selected in this group after collecting information about demographic and salivary samples from 3 to 5 cc before being informed. Saliva samples are taken to measure cortisol concentrations between 8:30 and 7:30 in the morning. Brushing and eating and drinking is not allowed for the client for half an hour before taking saliva. Samples are immediately sent to the laboratory and freeze at -20 ° F. Then it is centrifuged at 2500 rpm and ultimately measured by ELISA and using the kit of salivary cortisol. Then, the DASS-21 anxiety inventory questionnaire will be completed by patients with the presence of the researcher. The control group only receives routine pre-surgical training information. Then again, collect the saliva and complete the DASS-21 questionnaire.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
مجتمع بیمارستانی امام خمینی

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Tehran 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
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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
The total potential data can be shared after unidentifiable individuals
When the data will become available and for how

long

Get started 6 months after printing results

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

Post-print results will be announced

From where data/document is obtainable

Library of the Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

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

Post-print results will be announced

Comments