

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

Name

sara pakzadkaramad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7751 4933

Email address

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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		Other design features	
Public title The effect of provision of information on anxiety before surgery in patients with breast cancer		Secondary Ids empty	
Purpose Supportive		Ethics committees	
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		1 Ethics committee Name of ethics committee کمیته اخلاق در پژوهش های زیست پزشکی Street address Tehran University of Medical Sciences.,Dr Mirkhani St. (Eastern Nusrat).,Tohid Square City تهران Province Tehran Postal code 1419733171 Approval date 2018-11-06, 1397/08/15 Ethics committee reference number IR.TUMS.FNM.REC.1397.144	
Age From 18 years old to 60 years old		Health conditions studied	
Gender Female		1 Description of health condition studied Breast Cancer ICD-10 code ICD-10 code description	
Phase N/A		2 Description of health condition studied Salivary cortisol ICD-10 code ICD-10 code description	
Groups that have been masked No information		3 Description of health condition studied Anxiety before surgery ICD-10 code ICD-10 code description	
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		Primary outcomes	
Randomization (investigator's opinion) Randomized		1 Description Measuring the salivary cortisol Timepoint ۶۷/۵۰۰۰ Measure 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	
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			

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 intervention پرسشنامه

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

sara pakzad karamad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mojdeh Navid Hamidi

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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**

Tehran University of Medical Sciences

Full name of responsible person

sara pakzad karamad

Position

masters student

Latest degree

Master

Other areas of specialty/work

Nursery

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Latest degree

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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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

sara pakzad karamad

Position

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Latest degree

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Other areas of specialty/work

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City

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