

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of rhythmic breathing exercise on nausea and vomiting due to chemotherapy in breast cancer patients

Protocol summary

Study aim

The effect of regular breathing technique on chemotherapy-induced nausea and vomiting in breast cancer patients will be determined.

Design

These steps include: Lying on the bed, placing your right hand on your chest and your left hand on your abdomen, taking a deep breath through your nose for three seconds, to see how your abdomen inflates and your upper chest stretches. Can be noted, then exhale slowly for four seconds, this action is done through the clock in the ward. The patient is asked to do this 10 times slowly and in situations where Note your inhale and exhale. This technique should be performed by the patient as soon as he or she feels chemotherapy-induced nausea. To ensure patient learning, regular breathing techniques are practiced for each patient under the supervision of a researcher. Because focusing on the diaphragm may not be palpable to the patient, focusing on the abdomen is used instead of the term diaphragm in teaching regular breathing techniques.

Settings and conduct

All breast cancer patients undergoing chemotherapy in Khansari hospital in Arak will be educated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The person is undergoing chemotherapy with Adriamycin- Cyclophosphamide regimen. The person has taken at least one dose of chemotherapy and experienced nausea and vomiting afterwards. The person does not have digestive disorders. The person is not diagnosed with anxiety disorders and depression

Intervention groups

These patients are trained after the patients in the intervention group received the initial dose last month and experienced nausea and vomiting. Thus, before starting the second dose of chemotherapy, the technique of regular breathing is taught in the manner of abdominal breathing along with routine interventions. In

this technique, you have to focus on the diaphragm to breathe.

Main outcome variables

Nausea, Vomit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200521047526N1**

Registration date: **2020-11-10, 1399/08/20**

Registration timing: **retrospective**

Last update: **2020-11-10, 1399/08/20**

Update count: **0**

Registration date

2020-11-10, 1399/08/20

Registrant information

Name

Hamidreza karimifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3425 2349

Email address

hamidrezakarimifard91@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2020-10-01, 1399/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of rhythmic breathing exercise on nausea and vomiting due to chemotherapy in breast cancer patients

Public title

The effect of rhythmic breathing exercise on nausea and vomiting due to chemotherapy in breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The person is undergoing chemotherapy with Adriamycin-Cyclophosphamide regimen. The person has taken at least one dose of chemotherapy and experienced nausea and vomiting afterwards. The person does not have digestive disorders. The person is not diagnosed with anxiety disorders and depression

Exclusion criteria:**Age**

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected from outpatient chemotherapy patients first by purposive method and then by block randomization method by first preparing 6 blocks of 6 as follows: AAAAAA, AAAAAB, AAAABB, AAABBB, These blocks are randomly assigned to two groups according to A and B without regular placement. This action continues continuously until the sample size is completed.

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**

Ethics committee of Arak University of Medical Sciences

Street address

University Complex of the Great Prophet (PBUH), Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3813899589

Approval date

2020-04-28, 1399/02/09

Ethics committee reference number

IR.ARAKMU.REC.1399.019

Health conditions studied**1****Description of health condition studied**

Malignant neoplasm of breast

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Nausea

Timepoint

It should be noted that patients have been advised to perform the above technique immediately whenever they feel nauseous within 72 hours after the second round of chemotherapy. In his first contact (uniformly at 10 pm after the second round of chemotherapy), the researcher asked the patient about the first severity of nausea after performing the regular breathing technique in the last 12 hours with the VAS questionnaire (result of intervention in this part of the patient's severity of nausea). Then at the same time and every 12 hours every 3 days the Rhodes questionnaire (6 times) will be completed (the result of intervention in this section is the total score of the Rhodes questionnaire from the occurrence of nausea and vomiting every 12 hours). In fact VAS questionnaire only 1 time at 12 hours after chemotherapy will be accomplished and Rhodes questionnaire 6 times per 12 hours during 3 days will be filled.

Method of measurement

Questionnaire and Index of Nausea and Vomiting Form 2 (INV-2)

2**Description**

Vomiting

Timepoint

It should be noted that patients have been advised to perform the above technique immediately whenever they feel nauseous within 72 hours after the second round of chemotherapy. In his first contact (uniformly at 10 pm after the second round of chemotherapy), the researcher asked the patient about the first severity of nausea after performing the regular breathing technique in the last 12 hours with the VAS questionnaire (result of intervention in this part of the patient's severity of nausea). Then at the same time and every 12 hours every 3 days the Rhodes questionnaire (6 times) will be completed (the result of intervention in this section is the total score of the Rhodes questionnaire from the occurrence of nausea and vomiting every 12 hours). In fact VAS questionnaire only 1 time at 12 hours after chemotherapy will be accomplished and Rhodes questionnaire 6 times per 12 hours during 3 days will be filled.

Method of measurement

Questionnaire and Index of Nausea and Vomiting Form 2 (INV-2)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: These patients are trained after the patients in the intervention group received the initial dose last month and experienced nausea and vomiting. Thus, before starting the second dose of chemotherapy, the technique of regular breathing is taught in the form of abdominal breathing along with routine interventions. In this technique, you have to focus on the diaphragm to breathe. The steps of this technique will be fully explained to the patient by the researcher. These steps include: Lying on the bed, placing your right hand on your chest and your left hand on your abdomen, taking a deep breath through your nose for three seconds, to see how your abdomen inflates and your upper chest stretches. Can be noted, then exhale slowly for four seconds, this action is done through the clock in the ward. The patient is asked to do this 10 times slowly and in situations where Note your inhale and exhale. This technique should be performed by the patient as soon as he or she feels chemotherapy-induced nausea. To ensure patient learning, regular breathing techniques are practiced for each patient under the supervision of a researcher. Because focusing on the diaphragm may not be palpable to the patient, focusing on the abdomen is used instead of the term diaphragm in teaching the technique of regular breathing.

Category

Treatment - Other

2

Description

Control group: There are people in the study for whom

only standard methods of treating the side effects of chemotherapy are considered.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khansari Hospital

Full name of responsible person

Hamidreza Karimifard

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2

Recruitment center

Name of recruitment center

Imam Reza Specialized Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Hamidreza Karimifard

Position
Nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to

make this available
Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available