

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 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**

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**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

###### **Street address**

Shahid Shiroodi St.

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Arak

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info@arakmu.ac.ir

#### **2**

##### **Recruitment center**

###### **Name of recruitment center**

Imam Reza Specialized Clinic

###### **Full name of responsible person**

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Imam Reza Specialized Clinic, Shahid Shiroodi St.

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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**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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