Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Adriamycine- 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

Street address
Shahid Shiroodi St.

City
Arak

Province
Markazi

Postal code
3813899589

Phone
+98 86 3336 7500

Email
info@arakmu.ac.ir

2

Recruitment center

Name of recruitment center
Imam Reza Specialized Clinic

Full name of responsible person
Hamidreza Karimifard

Street address
Imam Reza Specialized Clinic, Shahid Shiroodi St.

City
Arak

Province
Markazi

Postal code
3813899589

Phone
+98 86 3313 3402

Email
info@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Alireza Kamali

Street address
Shahid Shiroodi St.

City
Arak

Province
Markazi

Postal code
3848176341
Phone
+98 86 3313 6055
Email
info@arakmu.ac.ir
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
Street address
Shahid Shiroodi St.
City
Arak
Province
Markazi
Postal code
3813899589
Phone
+98 86 3313 6055
Email
Hamidrezakarimifard91@gmail.com

Person responsible for scientific 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
Street address
Shahid Shiroodi St.
City
Arak
Province
Markazi
Postal code
3813899589
Phone
+98 86 3313 6055
Email
Hamidrezakarimifard91@gmail.com
Web page address

Person responsible for updating data

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
Street address
Shahid Shiroodi St.
City
Arak
Province
Markazi
Postal code
3813899589
Phone
+98 86 3313 6055
Email
Hamidrezakarimifard91@gmail.com

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