

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of mandala staining on nausea, vomiting and dry heaves in women with breast cancer undergoing chemotherapy

Protocol summary

Study aim

The effect of mandala staining on nausea, vomiting and dry heaves in women with breast cancer undergoing chemotherapy

Design

Sampling is done by random method and allocation in two test and control groups by random block method, phase 2 study, including attrition, is done on 29 patients.

Settings and conduct

Sampling in Yas Hospital will be done by random method and block classification into intervention and control groups. Mandala design for coloring and Rhodes index for data collection before, 1 and 12 hours after chemotherapy is provided to the intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: under treatment with adriamycin and cyclophosphamide regimen, presence of nausea, vomiting, Exclusion criteria: stopping chemotherapy, undergoing radiotherapy during the study, using over-the-counter medications to control nausea. Suffering from other diseases with the complication of nausea and vomiting, taking narcotics or sedatives or other complementary methods, having a defect or disability in the dominant hand that prevents coloring.

Intervention groups

In second session of chemotherapy, the Rhodes Nausea, Vomiting and Burping Index is provided to both groups to be completed immediately, 1 and 12 hours after the end of chemotherapy by the patient or his caregiver. In the third session, simultaneously with the administration of pre-chemotherapy drugs (Cetiril and Dexamethasone), the questionnaire of the second session are taken, one of the mandala designs along with colored pencils are provided to the patients of the intervention group. Immediately, 1 and 12 hours after the end of chemotherapy, the Rhodes index is completed and delivered to the researcher in the fourth session. These steps will be repeated for the fourth session of chemotherapy.

Main outcome variables

nausea, vomiting and dry heaves

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220611055138N1**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **retrospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

Faezeh Ghorbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 5522 5151

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mandala staining on nausea, vomiting and dry heaves in women with breast cancer undergoing chemotherapy

Public title

The effect of mandala staining on nausea, vomiting and dry heaves in women with breast cancer undergoing chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 years and older Literacy for the patient or caregiver Interest and satisfaction to participate in the research Treated with adriamycin and cyclophosphamide Perform at least one chemotherapy session Nausea, vomiting and dry heaves in the first session of chemotherapy (self-report) Do not have another illness with nausea, vomiting and wheezing according to the file and self-report Do not take any other medication with nausea, vomiting and nausea as reported and self-report Do not use narcotics or sedatives according to the file and self-report Absence of cognitive and psychiatric disorders (according to the file) No impairment in vision and hearing No defects or disabilities in the dominant hand so as to prevent staining. Do not use self-medication or other complementary medicine to reduce nausea, vomiting and nausea

Exclusion criteria:**Age**From **18 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **58****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, the samples will be selected from the patients referred to Yas Hospital based on the inclusion criteria, and then they will be placed in 4-block tables according to the order of referral and divided into intervention and control groups. In order to prevent information leakage, the implementation method and study objectives will be introduced to the people of the intervention group along with the necessary explanations, in a separate room.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

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Telar 10, 17 shahrivar st, zirab, savadkooh, mazandaran

City

Babol

Province

Mazandaran

Postal code

4781955855

Approval date

2022-05-29, 1401/03/08

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.060

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

Nausea

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

2**Description of health condition studied**

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

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

Rhodes nausea, vomiting and dry heaves questionnaire score

Timepoint

In sessions two, three and four immediately, one hour and 12 hours after chemotherapy

Method of measurement

Nausea and vomiting Rhodes Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before the intervention: In the second session of chemotherapy, Rhodes nausea, vomiting and gag index are provided to the samples of both groups by providing complete explanations until immediately, one hour later and 12 hours after the end of chemotherapy by the patient Or their caregiver is completed and delivered to the researcher at the next chemotherapy session. Intervention: 1- Before the start of the third session, the researcher makes the necessary arrangements with the samples of the experimental group to attend half an hour before the start of chemotherapy. 2- In the third session, at the same time as prescribing the drugs before chemotherapy (ketril and dexamethasone), the researcher receives the questionnaire of the second session and gives one of the mandala designs along with the colored pencil to the patient in 20 minutes. May paint accurately. Immediately, one hour later and 12 hours after the end of chemotherapy, the Rhodes index is completed again by the patient or his caregiver and delivered to the researcher in the fourth session of chemotherapy. Steps one and two will be repeated for the fourth session of chemotherapy.

Category

Treatment - Other

2

Description

Control group: People assigned to the control group will not receive any intervention other than chemotherapy. In order to compare the data, the Rhodes index will be completed before, one and 12 hours after chemotherapy by the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Hospital

Full name of responsible person

Hengameh karimi

Street address

Yas Hospital, Nejat-Ollahi Street, Tehran, Iran.

City

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faezeghorbani97@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mehdi Rajabnia

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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

Babol University of Medical Sciences

Proportion provided by this source

50

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

Babol University of Medical Sciences

Full name of responsible person

Hengameh karimi

Position

Teacher

Latest degree

Master

Other areas of specialty/work

Nursery

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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)

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

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

Title and more details about the data/document

When the data will become available and for how long

To whom data/document is available

Under which criteria data/document could be used

From where data/document is obtainable

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

Comments