Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of aromatherapy with rosa Damascena essence on nausea and vomiting in patients with breast cancer undergoing chemotherapy

Protocol summary

Study aim

Determining Effect of aromatherapy with rosa Damascena essence on nausea and vomiting in patients with breast cancer undergoing chemotherapy.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3on 76 patients. Allocation software was used for randomization.

Settings and conduct

Women with breast cancer referred to Ayatollah Khansari Hospital in Arak will be included in the study if they are eligible and will be randomly divided into two groups of intervention and control. This study will be performed in a double-blind way so that the person who accommodate the provided packet, the person who Assess the outcome of the intervention and data Analyzer are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years،Having a severity of nausea above 3 cm using the 10 cm VAS scale, definitive diagnosis of breast cancer،Healthy sense of smell. Exclusion criteria:History of lung diseases such as asthma, allergies.History of liver and kidney diseas،Having mental illness،Having migraines and chronic headaches.

Intervention groups

Intervention group: given 3 pads, a dropper and rose essence with a purity of 40% from Kashan Parsian Company. After chemotherapy it should be taught to pour 6 drops from dropper content on the pad before serving each meal (morning noon Night) for 24 hours.and put it at a 30 cm distance of their nose and inhale its content for 20 minutes normally. Control group: distilled water should be inhaled instead of rose essence in a similar، droppers of the same shape, size.

Main outcome variables

Severity of nausea،frequency of vomiting،frequency of retching

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211117053090N1**
Registration date: **2022-01-22, 1400/11/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-22, 1400/11/02**
Update count: **0**

Registration date

2022-01-22, 1400/11/02

Registrant information

Name

Kiarash Tabaraei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 4332 3985

Email address

k.tabaraei@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-10, 1400/10/20

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of aromatherapy with rosa Damascena essence on nausea and vomiting in patients with breast cancer undergoing chemotherapy

Public title
The effect of aroma with rose damascena essence on nausea and vomiting of chemotherapy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of breast cancer by oncologist and pathologist Chemotherapy with drugs that cause moderate to severe nausea Having a nausea severity above 3 cm using the 10 cm VAS scale Healthy sense of smell Being over 18 years old

Exclusion criteria:
Having migraines and chronic headaches Having a history of asthma and allergy to rosa damacena History of drug and alcohol addiction Having mental illness Having liver and kidney disease

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are entered into the study by non-random(purposive) sampling according to the inclusion criteria.In this study, we will use the Restricted randomization method of block randomization. Blocked randomization is usually used to balance the number of samples allocated to each of the studied groups. This feature helps researchers to equalize the number of samples allocated to each of the studied groups in cases where basics analysis are required during the sampling process. All blocks are the same size, and in this two-group experiment we will have blocks of size 4 (including 2 participants in the intervention group and2 participants in the control group). Random allocation software is also used for randomization. These random sequence generation software in addition to simple randomization, are able to generate sequences by blocking method. To conceal, we use Allocation concealment, is a technique that ensures that random allocation sequences are performed without knowing which patient will receive which treatment. Using sealed envelopes with random sequence (envelopes opaque, sealed, numbered sequentially),each of the random sequences created is recorded on a card and the cards are placed inside the envelopes. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box، respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
After obtaining the written consent of the participants, the prepared packages including (dropper containing distilled water, rose essence in the same shape and size as in the paper packages, pads and pins) will be given to the patients after the completion of their chemotherapy. They are taught how to use the contents of the package at home. In this way, there is no communication and contact between the participants of the intervention and control group. No odor from the dropper can be spread in the hospital that cover with a paper box. 1. One who (except researcher) accommodate the provided packets in the same shapes and sizes to the patients، whether the which packet is placebo or intervention is uninformed. 2. The person involved in information analysis is not involved in collecting information after the intervention. 3. The person who contacts the participants to evaluate the outcome of the intervention is unaware of the allocation of participants into two groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of Arak University of Medical Sciences

Street address
Code3848176341 ,Arak University of Medical Sciences،Next to Amir Al-Momenin Hospital، Basij Square،Phone:086-34173639

City
Arak

Province
Markazi

Postal code
3848176341

Approval date
2021-11-22, 1400/09/01

Ethics committee reference number
IR.ARAKMU.REC.1400.199

Health conditions studied

1

Description of health condition studied
Chemotherapy-induced nausea and vomiting in breast cancer

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Severity of Nausea
Timepoint
15 minutes before the start of chemotherapy (initially study) and 24 hours after the intervention.
Method of measurement
Visual Analogue Scale

2

Description
The frequency of vomiting
Timepoint
15 minutes before the start of chemotherapy (initially study) and 24 hours after the intervention.
Method of measurement
Rhodes Index

3

Description
The frequency of retching
Timepoint
15 minutes before the start of chemotherapy (initially study) and 24 hours after the intervention.
Method of measurement
Rhodes Index

Secondary outcomes

1

Description
Amount of vomiting
Timepoint
15 minutes before the start of chemotherapy (initially study) and 24 hours after the intervention .
Method of measurement
Rhodes Index

2

Description
Distress score of vomiting
Timepoint
15 minutes before the start of chemotherapy (initially study) and 24 hours after the intervention.
Method of measurement
Rhodes Index

3

Description
Distress score of retching
Timepoint
15 minutes before the start of chemotherapy (initially study) and 24 hours after the intervention
Method of measurement
Rhodes Index

4

Description
Total score of retching
Timepoint
15 minutes before the start of chemotherapy (initially study) and 24 hours after the intervention
Method of measurement
Rhodes Index

5

Description
Total score of vomiting
Timepoint
15 minutes before the start of chemotherapy (initially study) and 24 hours after the intervention
Method of measurement
Rhodes Index

Intervention groups

1

Description
Intervention group: 38 women with breast cancer participated in the study according to the inclusion criteria. Each participant was given a package containing 20ml dropper bottle (containing rose essence prepared by parsian (Medina Al-Nabi) Company with a purity of 40%) ، three pads (10 *10 cm) and a pin. After completing chemotherapy ،it should be taugh to pour 6 drops of dropper bottle content after going to home،which include rose essence of 40%purity on the pad and every given pad for every turn،before serving each main meal(morning, noon, and night) during 24 hours in a 30cm distant of their nose attached to their collar of clothes by a pin.This procedure was performed three times a day (morning, noon, and night). After the intervention (24 hours after chemotherapy), by phone Or face-to-face، Rhodes and VAS questionnaires are filled out to measure nausea and vomiting and sent to the data analyst.
Category
Rehabilitation

2

Description
Control group: 38 women with breast cancer who participated in the study according to inclusion criteria. A package containing a 20 ml dropper bottle (containing distilled water), three pads (10 x 10 cm) and a pin given to participants . After completing chemotherapy it shoud be taugh to Pour 6 drops of the contents of the dropper bottle after going to home،which include distilled water on the pad and every given pad for every turn،before serving each main meal(morning, noon, and night)

during 24 hours in a 30cm distant of their nose attached to their collar of clothes by a pin.This procedure was performed three times a day (morning, noon, and night) After the intervention (24 hours after chemotherapy), by phone Or face-to-face Rhodes and VAS questionnaires are filled out to measure nausea and vomiting and sent to the data analyst.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Khansari Hospital

Full name of responsible person
Kiarash Tabaraei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Kiarash Tabaraei

Position
Master student of intensive care nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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