Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Determining the effect of hand reflexology on chemotherapy-induced nausea and vomiting in patients with breast cancer

Protocol summary

Study aim
Investigating the effect of hand reflexology on chemotherapy-induced nausea and vomiting in breast cancer patients

Design
The clinical trial has an intervention and control group, double-blinded and randomized, which will be conducted on patients with breast cancer undergoing chemotherapy

Settings and conduct
Chemotherapy often causes nausea and vomiting, requiring effective management. This study involves breast cancer patients undergoing chemotherapy at Imam Hossein Hospital, Torbat Heydariyeh. Participants are randomized in blocks of 4 into two groups. Reflexology will be performed for both groups immediately after chemotherapy, for four weeks. The double-blind trial applies similar interventions to both groups, with non-real points in controls and real points in the intervention group. Both patients and the administrator are blinded to group allocation.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Confirmed diagnosis of breast cancer and undergoing chemotherapy with drugs that have moderate to high emetogenic potential. First cycle of chemotherapy. Literacy. No wounds on the hand area. No use of antiemetic drugs other than those prescribed by the treating physician in the ward. No history of diseases that cause vomiting, such as liver failure, gastrointestinal disorders, acute phase of hepatitis B and etc. Exclusion Criteria: Not being in the first cycle of chemotherapy. Presence of wounds or injuries on the hand area. Presence of diseases leading to vomiting.

Intervention groups
In the intervention group, reflexology will be performed on points on the hand that are effective in reducing nausea and vomiting weekly for four weeks immediately after chemotherapy drug injection. In the control group, reflexology will be performed on points on the hand that are not effective in reducing nausea and vomiting.

Main outcome variables
Nausea and vomiting

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190625044009N3**
Registration date: **2025-07-10, 1404/04/19**
Registration timing: **prospective**

Last update: **2025-07-10, 1404/04/19**
Update count: **0**

Registration date
2025-07-10, 1404/04/19

Registrant information
Name
Mahla Rajabzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3601 6795
Email address
rajabzadehm951@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-08-23, 1404/06/01
Expected recruitment end date
2026-03-16, 1404/12/25
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Determining the effect of hand reflexology on chemotherapy-induced nausea and vomiting in patients with breast cancer

Public title
The effect of hand reflexology on chemotherapy-induced nausea and vomiting

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of breast cancer and chemotherapy with drugs that are moderately to severely emetic First course of chemotherapy Being literate No wounds on the hand Do not use anti-nausea and anti-vomiting medications other than those prescribed in the ward by treating physician. Not having diseases that can lead to vomiting, such as liver failure, kidney failure, digestive disorders, acute phase of hepatitis B, gastrointestinal obstruction and Brain tumor

Exclusion criteria:
Lack of willingness of research units to continue participating in the study Needing intensive care Having a wound on the hands Change in chemotherapy drug protocols

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized blocks design with size 4 was used for randomization. A total number of 15 blocks of four were prepared. Then, the samples were assigned to intervention and control groups. A specific letter is assigned to each group to construct the allocation sequence (A: Intervention Group, B: control Group). The allocation sequence will then be generated using online methods (https://www.sealedenvelope.com/simple-randomiser/v1/lists) without individual intervention. Next, the sequence is written on the sheets and placed in sealed envelopes, respectively to conceal the allocation sequence and participants will receive envelopes in the order they enter the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
The intervention is performed similarly for both groups (control and intervention); however, the intervention points in the control group are applied at non-real points, while in the intervention group they are applied at real points. Therefore, the patients are unaware of which group they have been assigned to and are blinded to the type of intervention they receive. Additionally, the individual responsible for administering the intervention opens the envelopes containing the randomized sequence based on their numbering and performs the intervention. This person is blinded to the type of intervention assigned to each group (control or intervention).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Torbat Heydariyeh University of Medical Sciences

Street address
Torbat Heydariyeh University of Medical Sciences, Mehr Boulevard, Valiasr Town

City
Torbat Heydariyeh

Province
Razavi Khorasan

Postal code
9516160061

Approval date
2025-05-18, 1404/02/28

Ethics committee reference number
IR.THUMS.REC.1404.006

Health conditions studied

1

Description of health condition studied
Chemotherapy-induced nausea and vomiting

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Chemotherapy-induced nausea and vomiting

Timepoint

During each of the four weeks of treatment, immediately after the chemotherapy drug injection (pre-test) and 24 hours after the massage (post-test)

Method of measurement

Rhodes Index of Nausea and Vomiting

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The researcher will first wash the hands with warm water and remove jewelry, including watches and rings. The patient will remain in a sitting position. The researcher will begin a general massage with his thumb, starting at the patient's left forearm, then moving to the wrist, palm, back of the hand, and finally the fingers. The massage will be repeated eight to ten times. After the general hand massage, four reflexology points will be used for stimulation. The reflexology points include pericardium 6 on the inner surface of the wrist, approximately two finger widths above the skin fold of the wrist, the small intestine located on the back of the hand, in the triangular space between the metacarpal bones of the thumb and index finger, pericardium 7 just above the first fold of the wrist, and pericardium 8 on the center of the palm, where the tip of the middle finger reaches when making a fist. The researcher will press each of the reflexology points with his thumb until the patient feels pressure but does not feel pain. The duration of the massage for each point is two minutes, for a total of 16 minutes for both hands.

Category

Treatment - Other

2

Description

Control group: Control group: First, the researcher washes the hands with warm water and removes jewelry, including watches and rings. The patient will remain in a sitting position. The researcher will start a general massage with his thumb and the patient's left forearm, then move to the wrist, palm, back of the hand, and finally the fingers. The massage will be repeated eight to ten times. After the general hand massage, four reflexology points will be used for stimulation. The reflex points include the hypothenar point located on the fleshy prominence of the palm and under the little finger, the base of the fourth finger located on the palm, just below the metacarpal joint of the ring finger, the inner edge of the wrist located on the inner (ulnar) side of the wrist, about 2 centimeters below the wrist crease, and the back of the hand between the third and fourth fingers located on the dorsal surface of the hand, in the hollow between the metacarpal bones of the ring and little fingers, about one-third of the way to the wrist. The researcher presses each reflexology point with his thumb until the patient feels pressure but no pain. The duration of the massage for each point is two minutes, for a total of 16 minutes for both hands.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Hospital

Full name of responsible person

Amir Sadeq Al-Husseini

Street address

Imam Hossein Hospital, 5th kilometer of Torbat Heydariyeh to Mashhad road

City

Torbat Heydariyeh

Province

Razavi Khorasan

Postal code

9519140001

Phone

+98 51 5242 0000

Email

ihh@thums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Seyyed Mohammad Ahmadi Soleimani

Street address

Torbat Heydariyeh University of Medical Sciences, Mehr Boulevard, Valiasr Town

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9516160061

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thums_edu@thums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Torbate-Heidaria 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

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Mohammad Namazinia

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mahla Rajabzadeh

Position

PhD student in nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Person responsible for updating data

Contact

Name of organization / entity

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Position

PhD student in nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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City

Sari

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Postal code

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rajabzadehm951@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Currently, no decision has been made in this regard by the team

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available