Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of auriculotherapy and foot reflexology on chemotherapy-induced nausea and vomiting among women with breast cancer

Protocol summary

Study aim

Comparison of the effect of auriculotherapy and reflexology on chemotherapy-induced nausea and vomiting in breast cancer patients

Design

In a clinical trial with a control group, with parallel groups, one-way, blinded, randomized, on 105 patients, the permutation blocking method was used for randomization.

Settings and conduct

The intervention is performed in Iran Mehr Hospital in Birjand. After introducing oneself and the intended goals and obtaining informed written consent, the demographic information form is completed by the researcher in the form of an interview. Immediately after chemotherapy, the Rhodes questionnaire will be conducted for them. Then, patients with the permutation blocking method are divided into three groups: auricular therapy, reflexology, and control (patients do not know which group they are in). The marked points on the soles of the feet or earlobes are massaged with the help of a female researcher. Then, 6, 12, and 24 hours after the intervention, the patient is contacted, and the researcher fills in the questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Participants have the consent and full consciousness, Have organ health in the legs and ears, The patient can understand, read, write and speak Persian, The patient is being treated and has received at least one course of chemotherapy, The patient is not undergoing other studies or treatments at the same time, An oncologist makes the diagnosis of breast cancer; Exclusion criteria: the patient does not have the desire to participate in the study, the patient has mental problems, blindness, deafness, or a history of psychological issues, the patient does not feel nauseous after chemotherapy, the patient is undergoing other studies or treatments at the same time, the patient is not fully conscious.

Intervention groups

In the foot reflexology group, specific points are massaged by hand, and in the oriclo therapy group, particular points are massaged in the earlobe. No intervention is performed for the control group; they receive only routine medications.

Main outcome variables

Improving chemotherapy-induced nausea and vomiting in breast cancer patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220530055026N1**
Registration date: **2022-11-01, 1401/08/10**
Registration timing: **retrospective**

Last update: **2022-11-01, 1401/08/10**
Update count: **0**

Registration date

2022-11-01, 1401/08/10

Registrant information

Name

Behrooz Shayestepoor

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

behruzshy2015@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01
Expected recruitment end date
2022-07-22, 1401/04/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of auriculotherapy and foot reflexology on chemotherapy-induced nausea and vomiting among women with breast cancer

Public title
Comparison of the effect of auriculotherapy and foot reflexology on chemotherapy-induced nausea and vomiting among women with breast cancer
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Participants have the consent to participate in the study Have organ health in the legs in the reflexology group Have organ health in the eardrum in the auricular therapy group The patient is fully conscious The patient can understand, read, write and speak Persian. The patient is being treated and has received at least one course of chemotherapy The patient is not undergoing other studies or treatments at the same time The diagnosis of breast cancer is made by an oncologist The results of diagnostic tests have been confirmed by an oncologist
Exclusion criteria:
The patient does not have the desire to participate in the study The patient has mental problems, blindness, deafness, or a history of psychological issues The patient does not feel nauseous after chemotherapy The patient is undergoing other studies or treatments at the same time The patient is not fully conscious
Age
From **30 years** old to **70 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
They are randomly assigned to three groups control, foot reflexology intervention, and auricular therapy intervention by permutation blocking method.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants will not know which group they are going to be in. Before the intervention, the permutation blocking method determines in which of the three control groups the participant will be placed, foot reflexology intervention or auricular therapy intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences
Street address
No.30,Central Organization of Birjand University of Medical Sciences, Ghaffari Ave.,
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Approval date
2022-02-20, 1400/12/01
Ethics committee reference number
IR.BUMS.REC.1400.273

Health conditions studied

1

Description of health condition studied
Chemotherapy-induced nausea and vomiting in women with breast cancer
ICD-10 code
C50
ICD-10 code description
نئوپلاسم بدخیم پستان

Primary outcomes

1

Description
Nausea and vomiting score in Rhodes questionnaire INV 2
Timepoint
Before, 6 hours after, 12 hours after, 24 hours after the intervention
Method of measurement

Rhodes Nausea and Vomiting Questionnaire Form 2 (INV-2)

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: (foot reflexology), the trained person will wash his hands with antibacterial soap after washing the feet and placing the patient in the supine position to support the joint points and then reduce the irritation of the client's skin and the friction of the massage area. It is soaked in baby oil, and foot reflexology is performed continuously for 9 minutes. This massage is performed on one of the client's legs. Massage points include the spleen, stomach, and brain. Massage with a unique foot massage probe by applying moderate pressure on both sides of the upper and middle third of the sole (where the crease of the foot forms when the sole bends) along the second toe and the big toe deeply, causing Do not bother the patient (about 4 kg of alternating pressure for 5 seconds and one second of rest). This way, the spleen point massage will be done for 3 minutes, the stomach area massage will be done for 3 minutes, and the brain area will be massaged for 3 minutes. Then Rhodes nausea and vomiting questionnaire form 2 (INV-2) in patients 6, 12, and 24 hours after the intervention is completed by telephone by the researcher with the client.

Category

Rehabilitation

2

Description

Second Intervention group (auriculotherapy): massage points include the spleen, stomach, and subcortex. A trained person first identifies the points to perform the intervention. In the next step, the researcher applies pressure on the selected topics with a unique ear massage probe on the mentioned points (alternating pressure of about one kilogram for 5 seconds with one second of rest). This massage is performed on one of the client's ears. So that the spleen point massage will be done for 3 minutes, 3 minutes massage of the stomach area, 3 minutes massage of the area related to the subcortex in the sole. Auriculotherapy is performed continuously for 9 minutes. In patients 6, 12, and 24 hours after the intervention, the researcher completes a telephone call to the client.

Category

Rehabilitation

3

Description

Control group: Routine care will be performed for the control group. In addition, for this group, filling in the Rhodes questionnaire is completed similarly to the last two groups (in terms of completion time and several examinations) by the researcher.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranmehr Birjand Hospital

Full name of responsible person

Gholam Hossein Mahmoudi Rad

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No 30, Ghafari Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

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

Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Gholam Hossein Mahmoudi Rad
Position
Faculty member and dean of the faculty
Latest degree
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Other areas of specialty/work
Health Promotion
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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
Not applicable