Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Investigating the effect of auricular acupressure on pain, quality of life and peripheral neuropathy caused by chemotherapy among the elderly with breast cancer referred to centers affiliated to Kerman University of Medical Sciences

Protocol summary

Study aim
Determining the effect of auricular acupressure on pain, quality of life and peripheral neuropathy caused by chemotherapy in elderly patients with breast cancer referred to centers affiliated to Kerman University of Medical Sciences.

Design
A randomized controlled clinical trial, with parallel groups, without blinding

Settings and conduct
Selection of 60 breast cancer patients in centers affiliated to Kerman University of Medical Sciences

Participants/Inclusion and exclusion criteria
Under chemotherapy, including taxane agents. Elderly over 65 years old. Reported a score greater than five on a numerical rating scale for pain symptoms in the past week(indicating more severe than average pain). The possibility of participating in the project for four weeks. The ability to communicate and the absence of speech and hearing problems. Exclusion:12months or more have passed since the end of their chemotherapy treatment. Skin inflammation, use of hearing aids and piercings or holes in the intervention site. were undergoing chemotherapy or radiotherapy during the study period. Experienced ear acupressure within 3 months before attending Study. Metastatic cancer status. Having psychiatric diseases or other diseases that can affect this study

Intervention groups
Ear acupressure intervention will be performed for three weeks in the intervention group, and plant seeds will be stuck on the ear for the first 5 days of each week, and then removed for 2 days to rest. In the control group, to clearly determine the effectiveness of ear acupressure, reduce bias and create blinding between the participants, Plant seeds will be used on different ear points, where these points are not related to CIPN. The questionnaire will be completed before, immediately after the end of the intervention and two weeks after the end of the intervention.

Main outcome variables
Pain, quality of life and peripheral neuropathy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211213053389N2**
Registration date: **2024-10-24, 1403/08/03**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-24, 1403/08/03**
Update count: **0**

Registration date
2024-10-24, 1403/08/03

Registrant information

Name
mohammad hossein khajehpoor

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-10-12, 1403/07/21

Expected recruitment end date

2025-01-19, 1403/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of auricular acupressure on pain, quality of life and peripheral neuropathy caused by chemotherapy among the elderly with breast cancer referred to centers affiliated to Kerman University of Medical Sciences

Public title

Investigating the effect of auricular acupressure on pain, quality of life and peripheral neuropathy caused by chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Undergoing chemotherapy, including taxane agents (such as docetaxel and paclitaxel) Elderly over 65 years old Reported a score greater than five on a numerical rating scale for pain symptoms in the past week (indicating more severe than average pain) Possibility to participate in the plan for four weeks The ability to communicate and the absence of speech and hearing problems

Exclusion criteria:

12 months or more have passed since the end of their chemotherapy treatment They had skin inflammation, or used hearing aids, or had piercings or holes in the intervention sites During the study period, they are under chemotherapy or radiotherapy Ear acupressure experience within 3 months before participating in the study Metastatic cancer status Have psychiatric diseases or other diseases that can affect this study (Alzheimer's, delirium, rheumatoid arthritis)

Age

From **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be selected by continuous sampling, and patients will be divided into control and test groups by Block Balanced Randomization (BBR). The allocation sequence will be done using the free web system http://www.randomization.com/. In this way, the number of subjects in each block is determined by 4 people and the letter A will be considered for the control group and the letter B will be considered for the experimental group. The assignment sequence will be created for 60 samples by combining the letters A and B. Finally, the cards containing the blocks will be placed inside the standard envelope, and as a result, the Allocation Concealment will be considered and observed. Based on the eligible samples, an envelope shuffling envelope will be randomly removed by the researcher, and the method of randomly assigning the research samples will be determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

Because Vacaria seeds are placed by the researcher on different points on the ear in both the control and intervention groups, and the participants are blind about which group they are in, and the elderly participants will not be informed which intervention group they are in. or are in control. On the other hand, the participants do not know the location of the reflective points of the intervention, it is expected that there will be no interference between the participants of the two control and intervention groups. However, the participants of the intervention group are informed not to pass on the information about the reflective points on the ear to other participants. In this study, the participants and the statistician for data analysis are blinded to the members of each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Beginning of Ibn Sina Street, first Jihad Blvd., Somayeh intersection, Kerman

City

Kerman

Province

Kerman

Postal code

7815789957

Approval date

2024-10-09, 1403/07/18

Ethics committee reference number

IR.KMU.REC.1403.290

Health conditions studied

1

Description of health condition studied
Breast Cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Chemotherapy-induced peripheral neuropathy score in Chemotherapy-Induced Peripheral Neuropathy-20 (CIPN-20), health-related quality of life score in Functional Assessment of Cancer Therapy-General (FACT-G), pain score in The Numeric Rating Scale
Timepoint
Questionnaires are given to the participants before the intervention, immediately after the end of the intervention and two weeks after the end of the intervention, or they are completed with an interview.
Method of measurement
Chemotherapy-Induced Peripheral Neuropathy-20 questionnaires (CIPN-20), Functional Assessment of Cancer Therapy-General questionnaires (FACT-G), The Numeric Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, auricular acupressure will be applied on 3 common ear points, including the spleen, liver, and spleen, and 1 point related to the finger or toe points will be added, based on each participant's understanding of the severity of the symptoms in the specific hand or foot location. will be selected. As a main point, Shenman is widely used in sick and healthy populations to treat physical and mental problems. Stimulating both liver and spleen points increases metabolism because these points play a role in reducing the neurotoxic effects of chemotherapy. Because direct pressure on the reflex points of the symptomatic parts of the body on the ear helps to relieve the pain level, 1 point out of 2 points, i.e. finger or toe point, will be selected for use in the intervention group. Vacaria plant has small black seeds, which are used in ear acupressure due to the hardness of the seeds to apply pressure on specific points on the ear, and Vacaria plant seeds also have anti-inflammatory properties in ear acupressure. Vaccaria seeds will be used for proper and long-term stimulation, which is widely used and will be placed bilaterally at target points on both ears at the same time. Considering the possible benefits and risks, the ear acupressure intervention will be performed for three weeks, and we stick the herbal seeds on the ear every week for the first 5 days, and then rest for 2 days, and then remove the herbal seeds. And thus, the patient will undergo acupressure for three consecutive weeks. Due to the long-term use of adhesive tapes, the ear points are rested before replacing new beads to avoid side effects such as contact dermatitis. The elderly were instructed to press each ear point for 2 minutes (1 second per pressure) at least 3 times a day, for 5 consecutive days. Pressure levels will be adjusted depending on the tolerance of the elderly. First, the designated points on the patient's ear are cleaned with 70% alcohol, and then adhesives with Vacaria plant seeds (0.5 x 0.5 cm) will be used to apply continuous pressure on the ear throughout the day and night, and the adhesive will be used. The plant seeds will be removed from the ear after five days, and if the plant seed paste is removed from the ear earlier than five days, the elderly will be asked to inform immediately so that the researcher can use the paste with new plant seeds again to apply continuous pressure. Participants who did not pay attention to the instructions in keeping plant seeds in specific places, which led to a decrease in the received dose (more than 10% of the intervention period or more than one day of the intervention period, plant seeds were removed from the ear will be excluded from the study.
Category
Prevention

2

Description
Control group: In the control group, to clearly determine the effectiveness of ear acupressure to reduce bias and create blinding between the participants, Vacaria plant seeds were placed on different ear points, including teeth, tongue, jaw, and inner ear, which will be located at a distance from the ear points in the intervention group. These points are not related to CIPN.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipur educational and therapeutic center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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https://vresearch.kmu.ac.ir/fa

Grant name

Grant code / Reference number

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

Title of funding source
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Mohammad hossein Khajehpour

Position
Faculty instructor, faculty member

Latest degree
Master

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