Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of ear acupressure on endocrine therapy-associated musculoskeletal pain in breast cancer survivors

Protocol summary

Study aim
Determining the effect of ear acupressure on musculoskeletal pain associated with endocrine therapy in breast cancer survivors

Design
A randomized, double-blind, controlled clinical trial study was performed on 52 patients for block randomization using the Sealed Envelope Ltd. 2017 software, available at www.sealedenvelope.com, with a total of 8 blocks, 4 blocks of 6 and 4 blocks of 8

Settings and conduct
The Persian version of the Short Pain Questionnaire will be completed at the beginning of the study, weekly until the end of the intervention for 4 weeks, and 4 weeks after the end of the intervention for the two groups through an interview with the individual by a colleague unaware of the status of the samples' allocation to the groups.

Participants/Inclusion and exclusion criteria
The main inclusion criteria included: diagnosis of stage 1 to 3 hormone-dependent breast cancer, without recurrence or metastasis, use of tamoxifen or aromatase inhibitors for at least 3 months, development or exacerbation of musculoskeletal pain, having pain with an intensity of at least 3 on a scale of 0 to 10 in the week before the start of the study،The main exclusion criteria for the study included: any type of surgery, musculoskeletal diseases, skin diseases (in the earlobe), orthopedic or neurological problems during the study, concomitant use of other complementary therapies, any lack of cooperation, death, allergy to the adhesive.

Intervention groups
In the intervention group, Vaccaria seeds will be applied to the points used to relieve stress and pain on both earlobes for four weeks, five days a week, three times a day (morning, noon, and night), with pressure applied to the points for three minutes each time. In the sham group, the patches will be applied without seeds and without applying pressure.

Main outcome variables
Musculoskeletal pain score

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20100211003329N13**
Registration date: **2025-10-27, 1404/08/05**
Registration timing: **prospective**

Last update: **2025-10-27, 1404/08/05**
Update count: **0**
Registration date
2025-10-27, 1404/08/05

Registrant information
Name
Zahra Sooki
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 5554 0021
Email address
sooki_za@kaums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-11-01, 1404/08/10
Expected recruitment end date
2026-01-30, 1404/11/10
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of ear acupressure on endocrine therapy-associated musculoskeletal pain in breast cancer survivors

Public title
The effect of ear acupressure on endocrine therapy-associated musculoskeletal pain in breast cancer survivors

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of stage 1 to 3 hormone-dependent breast cancer (histology report), without recurrence and metastasis to distant sites Taking tamoxifen or aromatase inhibitor drugs for at least 3 months The type of medication must be stable for at least 2 months before the start of the study. Development or worsening of musculoskeletal pain following initiation of endocrine therapy Experiencing musculoskeletal pain for at least 2 months and at least 15 days per month Having pain with an intensity of at least 3 on a scale of 0 to 10 (sensory dimension of the Persian version of the Short Pain Questionnaire) in the week before the start of the study Iranian nationality, resident of Kashan and its suburbs Postmenopausal (age 60 years or older, history of oophorectomy, history of hysterectomy, or amenorrhea for at least 12 months) At least 4 weeks have passed since the completion of surgical, chemotherapy, and radiotherapy treatments. Organ health in the earlobe area

Exclusion criteria:
Any type of surgery, musculoskeletal disease, orthopedic or neurological problems during the study Performing any type of intense physical activity or starting a sports activity during the study Use of corticosteroids or opioids during the study Allergy to glue Hospitalization due to physical or mental problems during the study Performing physiotherapy during the study Taking nutritional supplements during the study (except calcium and vitamin D) Changes in endocrine treatment plan during the study Combined use of other complementary therapies Withdrawal from further cooperation during the study Failure to meet the criteria regarding the average daily pressure applied to the heads during each week of intervention (less than 6 minutes per day) Experiencing serious stress, lack of access, death engaging in professional sports activities having fibromyalgia, arthritis and inflammatory arthritis requiring medication, active cancer, rheumatoid arthritis, peripheral nerve problems in the limbs, cognitive impairment, and lymphedema based on patient records and self-report. use of narcotics and corticosteroids using acupuncture in the past 6 months amputation, fracture, or bone surgery within the past 6 months

Age
From **18 years** old to **70 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible samples will be listed in order of screening and then randomly assigned to each of the two intervention and sham groups in blocks of 8 and 6. Using the Sealed Envelope Ltd. 2017 software available at www.sealedenvelope.com, 4 blocks of 6 and 4 blocks of 8 were defined, for a total of 8 blocks, and the allocation to groups will be done based on the order specified by the software.

Blinding (investigator's opinion)
Double blinded

Blinding description
The subject/participant is unaware of the nature of the seeds prescribed to her, and the person collecting the data is also unaware of the subject's group

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Faculty of Medicine & Faculty of Dentistry- Kashan University of Medic

Street address
Kashan University of Medical Sciences, Pezeshk Blvd, Qutb Rawandi Blvd, Kashan

City
Kashan

Province
Isfehan

Postal code
8715985191

Approval date
2025-10-15, 1404/07/23

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1404.128

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50-C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Musculoskeletal pain score

Timepoint

At the beginning of the study, after the end of the intervention, and 4 weeks after the end of the intervention

Method of measurement

Persian version of the Brief Pain Questionnaire

Secondary outcomes

1

Description

Pain interference score

Timepoint

weekely

Method of measurement

Report of patient

Intervention groups

1

Description

Intervention group: , the researcher will attach ZHONG YANG brand of Vakaria seeds made in China to the points used to relieve stress and pain (including Shenmen, Sympathetic, Subcortex, Antidepressant, Muscle Relaxation) on both earlobes, and the patient will be instructed to press each point using the thumb and forefinger to the extent that it causes mild discomfort.Pressure will be applied to the points for four weeks, five days a week, three times a day (morning, afternoon, and evening), and each time will last for a total of three minutes . In the sham group, adhesives will be applied to the desired points but without seed, and no pressure will be applied to them.It should be noted that during the 4-week intervention, stickers containing Vaccaria seeds in the intervention group and stickers without seeds in the sham group will be attached by the researcher to both ears simultaneously every week, after cleaning the skin with alcohol cotton.The stickers will be worn on the ears for five days a week, and the patient will be asked to remove the stickers at the end of the fifth day to prevent a possible allergic reaction. The patient will be instructed to contact the researcher if the stickers come off during the five-day period so that the researcher can reattach the stickers at an agreed-upon location (clinic, office, sample home, etc.).The subjects will be instructed to refrain from exercising, engaging in strenuous physical activity, and using nutritional supplements (except calcium and vitamin D) and other complementary therapies during the study period. If they take painkillers, they will be asked to record the type, dose, and number of times they take them daily.Also, if they experience any complications such as redness, inflammation, and itching in the earlobe area, they should record and report them. During the intervention, the individual will also be given a weekly diary sheet in which they will record the duration of each pressure point, the occurrence of allergic reactions, the use of painkillers, and the start of new medication.The contents of the daily note sheet are organized using visual symbols in a way that can be understood and completed by all subjects, both literate and illiterate, with simple training.During the intervention period, all participants will be visited at the agreed location each week and new labels will be applied to them, and a daily note sheet will be given to them and another sheet will be given to them for the following week. If in the intervention group the average daily duration of pressure on the testicles during each week of the intervention is less than 6 minutes, that person will be excluded from the study.The labeling will continue for 4 weeks and the samples will be followed up for 4 weeks after the end of the intervention. The Persian version of the Short Pain Questionnaire (sensory and reactive dimensions) will be completed at the beginning of the study, weekly until the end of the intervention, and 4 weeks after the end of the intervention for both groups through an interview with the individual by a collaborator who is not aware of the status of the samples' allocation to the groups.At the time of sampling, the telephone number and home address of the subjects were recorded, and during the intervention period, weekly coordination was made over the telephone regarding the time and place of the visit and, if necessary, transportation arrangements, as well as for the purpose of conducting follow-up 4 weeks after the end of the intervention.

Category

Treatment - Drugs

2

Description

Control group: In the sham group, the patches will be applied to the desired areas but without seed, and no pressure will be applied to them. It should be noted that during the 4-week intervention, the patches without seed in the sham group will be applied simultaneously to both ears every week by the researcher, after cleaning the skin with alcohol cotton.The stickers will be placed on the ears five days a week and the patient will be asked to remove the stickers at the end of the fifth day to prevent a possible allergic reaction. The patient will be instructed to contact the researcher if the stickers come off during the five-day period so that the researcher can reattach the stickers at an agreed location (clinic, office, sample home, etc.).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital, Kashan

Full name of responsible person
Hamed Pahlavani

Street address
Kashan - Qotb Ravandi Boulevard - Shahid Beheshti Hospital Complex

City
Kashan

Province
Isfehan

Postal code
87159/81151

Phone
+98 31 5554 0026

Email
beheshtihospital@kaums.ac.ir

2

Recruitment center

Name of recruitment center
Ayatollah Yathrabi Superspecialty Hospital

Full name of responsible person
Mustafa Sarvizadeh

Street address
Kashan, Qotb Ravandi Blvd., Parast Blvd., Ayatollah Yaserbi Superspecialty Hospital

City
Kashan

Province
Isfehan

Postal code
8715973454

Phone
+98 31 5558 5000

Email
info@yasrebihospital.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Dr. Gholam Ali Hamidi

Street address
Kashan University of Medical Sciences, Pezeshk Blvd, Ghotb Ravandi Blvd, Kashan

City
Kashan

Province
Isfehan

Postal code
8715985191

Phone
+98 31 5510 3529

Email
hamidi_gh@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Zahra Tagharrobi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Kashan University of Medical Sciences, Pezeshk Blvd, Qutb Rawandi Blvd, Kashan

City
Kashan

Province
Isfehan

Postal code
8715981151

Phone
+98 31 5510 3119

Fax
+98 31 5554 6633

Email
tagharrobi_z@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Zahra Tagharrobi

Position
Associate Professor

Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Kashan University of Medical Sciences, Pezeshk Blvd, Ghotb Ravandi Blvd, Kashan
City
kashan
Province
Isfehan
Postal code
8715985191
Phone
+98 31 5510 3119
Fax
+98 31 5554 6633
Email
tagharrobi_z@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zahra Sooki
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Kashan University of Medical Sciences, Pezeshk Blvd, Ghotb Ravandi Blvd, Kashan
City
Kashan
Province
Isfehan
Postal code
8715985191
Phone
+98 31 5510 3135
Fax
+98 31 5554 6633
Email
z.sooki@yahoo.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
Not done yet.
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