Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effects of acupressure points (P6, K-K9) on Nausea, Vomiting and anxiety of patients undergoing chemotherapy

Protocol summary

Study aim

Comparison of the effect of acupressure of points K-K9 and P6 on nausea, vomiting and anxiety of patients undergoing chemotherapy in Shahid Beheshti Hospital of Kashan city in 2023.

Design

A three-arm single-blind clinical trial with a control group, with parallel groups, randomized on 90 patients. For randomization, the stratified method and sealedenvelope.com website are used.

Settings and conduct

Interventions are performed in the special injections ward of Shahid Beheshti Hospital, Kashan. All three interventions are acupressure with instruments and will be performed before chemotherapy until five days after. Questionnaires are completed one hour after chemotherapy and up to 5 days after that. Patients are unaware of the actual intervention.

Participants/Inclusion and exclusion criteria

Main entry requirements 1) Patients 16 years and older; 2) Patients with a definite diagnosis of cancer; 3) Patients who mention having nausea in their previous chemotherapy period; 4) Patients who have received at least one cycle of chemotherapy; Main non-entry conditions: 1) Having concurrent radiotherapy; 2) Having a problem in the skin of acupressure points; 3) Not having any problems, including diseases that interfere with nausea and vomiting of chemotherapy; 4) Not having a known anxiety disorder.

Intervention groups

Interventions are performed in all three groups in addition to the usual treatments. In the case of the first to third groups, respectively, acupressure measures on point P6, point K-K9, and point Li5 will be performed bilaterally with special tools.

Main outcome variables

Nausea and vomiting; Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100829004655N12**
Registration date: **2023-05-04, 1402/02/14**
Registration timing: **prospective**

Last update: **2023-05-04, 1402/02/14**
Update count: **0**

Registration date

2023-05-04, 1402/02/14

Registrant information

Name

Mohsen Taghadosi

Name of organization / entity

Kashan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of acupressure points (P6, K-K9) on Nausea, Vomiting and anxiety of patients undergoing chemotherapy

Public title

Comparison of the effects of acupressure points on patients undergoing chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 16 years and older Patients with a definitive diagnosis of breast, colorectal, lung, prostate, and ovarian cancers by a specialist doctor Patients who mention having nausea in their previous chemotherapy period Patients who receive chemotherapy drugs by intravenous, port, or intravenous injection along with oral intake Patients who have received at least one cycle of chemotherapy

Exclusion criteria:

Undergoing radiotherapy at the same time as chemotherapy Using other complementary treatments at the same time Having a known anxiety disorder Having problems in the skin of acupressure points (for example, edema, lesions, or skin wounds) so that effective pressure cannot be applied Having problems such as gastrointestinal diseases with nausea and vomiting, migraines, and tinnitus that are related to before the start of chemotherapy and interfere with nausea and vomiting of chemotherapy. This case will be reviewed based on the patient's statement or medical record Patients who have a minimal risk of emesis chemotherapy regimen as determined by a specialist doctor.

Age

From **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

After reviewing the entry criteria (referring to the medical record and interviewing the individual), patients who are eligible to enter the study are randomly grouped. Each patient is placed in one of the groups P6, K-K9 and Li5 (placebo) according to the nausea-inducing level of chemotherapy drugs (low, medium and high). It should be noted that according to the table of nausea-inducing drugs, 4 general categories are considered for chemotherapy drugs, which include Minimal Risk of Emesis, Low Risk of Emesis, Moderate Risk of Emesis, and High Risk of Emesis. The minimal risk of emesis category is not included in the study. For example, the first qualified referral patient is treated with a three-drug regimen of 5FU (Fluorouracil), oxaliplatin and docetaxel; According to the table, these drugs are mild, moderate nauseating, and low nauseating. Due to the presence of a drug with moderate nausea (oxaliplatin), this patient is considered out of this category (moderate nausea). Referring to the blocks, this person is placed in group B, the same as K-K9. If the next person is considered part of the moderate nausea group, he will be placed in group A, the same group as P6. In the same way, the following people are assigned to three groups, P6, K-K9, and Li5, according to whether the amount of nausea caused by their drugs is low, medium, or high. Allocation of groups is done randomly using the stratified method based on the degree of nausea of the drugs and using the Sealedenvelope.com site. In this method, the size of the blocks is considered to be 6. The size of the list is considered to be 126 due to the equal distribution of each class among the three groups. In fact, by increasing the list size, samples from other classes can be included in the study if a class does not reach the quorum.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the interventions' observable nature, it is impossible to design the study in a completely blind manner. In this study, after giving informed consent to participate in the research, the participants will not know whether they are in the placebo group or the main groups, so the main names of the points are not told to the participants. Instead, general names such as A, B, and C are used. As a research team member, the nursing master's student is responsible for implementing interventions and collecting questionnaires and checklists, so there is no possibility of blinding in this case. The healthcare workers in the special injection ward of Shahid Beheshti Hospital in Kashan (including nurses) also do not know about the real intervention.

Placebo

Used

Assignment

Parallel

Other design features

Demographic information obtained includes first and last name, date of injection, age, gender, marital status, economic status, occupation, education, type of insurance, family history of cancer, alcohol consumption, and smoking and tobacco use. The obtained clinical information, which is completed by the patient or by referring to the medical record, also includes diagnosis, stage of the disease, duration of the disease, the number of cycles of chemotherapy, the method of receiving chemotherapy, the name and dosage of chemotherapy drugs. Treatment is the degree of nausea of the drugs, the name of the anti-nausea drugs and the dose received in the hospital and at home, the name of other drugs used, body mass index, history of surgery related to cancer, and other complications related to chemotherapy. If the patient needs help to complete the questionnaires, they will be completed by the researcher in the hospital.The drugs used as anti-nausea in these patients will be 4mg ondansetron ampoule, 8mg

dexamethasone ampoule, and Aprepitant oral capsule. It should be noted that during the study, each patient's chemotherapy and anti-nausea regimen will not change. The use of drugs to relieve nausea other than the mentioned drugs, if used in the hospital by the researcher and if used at home by the patient and in a checklist that we provide to him, will be registered.The exact location of acupressure points is taught to the patient by the researcher, and for this purpose, a pamphlet is also given to her to help her find the point at home.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committees of Faculty of Medicine and Faculty of Dentistry- Kashan University of Med

Street address
Ghotb Ravandi Blvd, Kashan

City
Kashan

Province
Isfehan

Postal code
8715981151

Approval date
2023-04-09, 1402/01/20

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1402.008

Health conditions studied

1

Description of health condition studied
chemotherapy

ICD-10 code
Z54.2

ICD-10 code description
Convalescence following chemotherapy

Primary outcomes

1

Description
Nausea, whose score is measured by the Rhodes Nausea and Vomiting Questionnaire (statements 4, 5, and 7).

Timepoint
One hour after chemotherapy and at the end of the first to fifth days of chemotherapy.

Method of measurement
The Rhodes Nausea and Vomiting Questionnaire.

2

Description
Vomiting, whose score is measured by the Rhodes Nausea and Vomiting Questionnaire (statements 1, 3, and 6)

Timepoint
One hour after chemotherapy and at the end of the first to fifth days of chemotherapy.

Method of measurement
The Rhodes Nausea and Vomiting Questionnaire.

Secondary outcomes

1

Description
Anxiety is measured by Spielberger's state-trait anxiety questionnaire

Timepoint
One hour after chemotherapy and at the end of the first to fifth days of chemotherapy

Method of measurement
The Spielberger's state-trait anxiety questionnaire

Intervention groups

1

Description
The first intervention group: pressure on the P6 point will be applied bilaterally by acupressure wrist straps. The wristbands are from the vomit-band brand and consist of a webbing with a button in the middle that puts pressure on the P6 point. Acupressure intervention will be done before chemotherapy until five days after. The patient is asked to remove the acupressure tools at the end of the day and before going to sleep and complete the special checklists designed for this study. The next day, he should use that tool again in the same place. This process should be done five days after the injection. It should be noted that he can remove them from his hands during bathing, washing hands, etc. After five days, the patient does not need to do anything else.

Category
Prevention

2

Description
The second intervention group: Applying pressure on the K-K9 point is done bilaterally by rings made of knitted fabric with a button in the middle (similar to the button of P6 wristbands). Acupressure intervention will be done before chemotherapy until five days after. The patient is asked to remove the acupressure tools at the end of the day and before going to sleep and complete the special checklists designed for this study. The next day, he should use that tool again in the same place. This process should be done five days after the injection. It should be noted that he can remove them from his hands during bathing, washing hands, etc. After five days, the

patient does not need to do anything else.

Category

Prevention

3

Description

Control group: Applying pressure on the Li5 point (placebo) using knitted wristbands, which apply pressure on the desired point bilaterally. The button that puts pressure on this point is similar to that on P6 wristbands. Acupressure intervention will be done before chemotherapy until five days after. The patient is asked to remove the acupressure tools at the end of the day and before going to sleep and complete the special checklists designed for this study. The next day, he should use that tool again in the same place. This process should be done five days after the injection. It should be noted that he can remove them from his hands during bathing, washing hands, etc. After five days, the patient does not need to do anything else.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti medical education Center of Kashan university of medical Sciences

Full name of responsible person

Mohsen Taghadosi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan 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

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

Mohsen Taghadosi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact
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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The total potential data can be shared after unidentifiable people
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Only available to scholars working in academia and academia.
Under which criteria data/document could be used
If you observe the trust and mention the source, data is available for researchers
From where data/document is obtainable
Send the following e-mail to the following address: taghadosi_m@kaums.ac.ir
What processes are involved for a request to access data/document
After receiving the letter via email, your request will be reviewed within 2 weeks and the data will be sent to the applicant at the discretion.
Comments