Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of zingiber and acupressure onchemotherapy induced nausea and vomiting (CINV) in patients with breast cancer

Protocol summary

Study aim
Comparison the effect of zingiber and acupressure on chemotherapy induced nausea and vomiting patients with breast cancer

Design
Controlled randomized clinical trial, with parallel groups, without blindness.

Settings and conduct
This is a randomized controlled clinical trial study in which four groups of Zingiberr, placebo of Zingiber, acupressure and placebo-acupressure will be done on 80 patients with breast cancer undergoing chemotherapy referring to hospitals affiliated to Tehran University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definite diagnosis of breast cancer; existing at least three cycles of chemotherapy. Exclusion criteria: Sensitivity to Zingiber; history of any abnormal hemorrhage; use of blood diluent drugs; coagulation disorders

Intervention groups
1) Zingiber group (receiving 500 mg of Vomigone tablets) 2) Zingiber placebo group (receiving placebo tablets similar to Vomigone tablets) 3) Acupressure intervention group (use of acupressure wristband at the point of neiguan or P6) 4) Acupressure placebo group (Use acupressure wrisbands in opposite site of the neiguan point)

Main outcome variables
Nausea and Vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120109008665N10**
Registration date: **2019-11-24, 1398/09/03**
Registration timing: **prospective**
Last update: **2019-12-21, 1398/09/30**
Update count: **1**

Registration date
2019-11-24, 1398/09/03

Registrant information

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Name of organization / entity
Semnan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-06-21, 1399/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of zingiber and acupressure onchemotherapy induced nausea and vomiting (CINV) in patients with breast cancer

Public title
Comparison of the effect of zingiber and acupressure on nausea and vomiting

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Detection of breast cancer by an oncologist and pathologist Age between 18 and 70 years The normal values of hematological and biochemical laboratory values in the Zingiber group The desire to participate in the study

Exclusion criteria:

Sensitivity to Zingiber and its consumption over the past week (at first use) The presence of sensitivity and ulcers or any skin problems at the site of use of acupressure wristband Use of blood diluent such as Aspirin, Warfarin, Heparin, Plavix and ... in the Zingiber group. Coagulation disorders (platelets less than 100,000/mm3, etc.) in the Zingiber group Receiving radiotherapy and chemotherapy simultaneously The diseases that lead to nausea and vomiting include liver, kidney, upper gastrointestinal cancer, acute hepatitis B, gastrointestinal obstruction, brain malignancies, high blood pressure, motion sickness, diabetes and electrolyte disorders such as hyponatremia and Hypokalemia Use of alcohol and opium The history of psychiatric problems in patients under treatment with acupressure wristband

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of samples to four groups (zingiber, acupressure, zingiber placebo and placebo of acupressure) will be done randomly using random blocks method. 10 blocks with 8 cases in each are created and every time randomly a block will be selected. In this method, A: represent zingiber group; B: acupressure; C: zingiber placebo; D: placebo of acupressure (false point).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences (SEMUMS), Vice Chancellor of Research and Technology , Bassij Blvd., Semnan, Iran

City

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Province

Semnan

Postal code

3519899951

Approval date

2019-12-17, 1398/09/26

Ethics committee reference number

IR.SEMUMS.REC.1398.212

Health conditions studied

1

Description of health condition studied

Nausea and Vomiting

ICD-10 code

R11.2

ICD-10 code description

Nausea with vomiting, unspecified

Primary outcomes

1

Description

severity of nausea and vomiting

Timepoint

Evaluation and measurements will be performed from the first day of chemotherapy up to 5 days after the completion of chemotherapy by the patient.

Method of measurement

Morrow Assessment of Nausea and Emesis (MANE)

2

Description

frequency of nausea and vomiting

Timepoint

Evaluation and measurements will be performed from the first day of chemotherapy up to 5 days after the completion of chemotherapy by the patient.

Method of measurement

Morrow Assessment of Nausea and Emesis (MANE)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All participants in Zingiber

intervention group, after assuring the results of the tests, in addition to the routine interventions prescribed by the physician, receive Vomigone pills (500 mg) Produced by Dineh Pharmaceutical Company for the first day of chemotherapy, half an hour before the injection of chemotherapy drugs, and the next time, at 9 o'clock of the same day. Continue taking tablets twice a day at 9 am and 9 pm, 5 days after the completion of chemotherapy. If the patient is raised, within two hours, the drug will be re-used.

Category

Prevention

2

Description

Intervention group: In the acupressure intervention group, in addition to the routine interventions prescribed by the physician, the acupressure wristbands will be closed in two hands for half an hour before starting the injection of drugs up to 5 days after the completion of chemotherapy in the neiguan (P6) point.

Category

Prevention

3

Description

Control group: In the Zingiber placebo group, placebo tablets similar to Vomigone tablets (size, shape, color, taste and dosage but lacking the active ingredient) will be used. The method is similar to the Zingiber group.

Category

Placebo

4

Description

Control group: In the acupressure placebo group, the wristbands will close on both sides of the arm on the wrist with a plastic point at the opposite point of the neiguan point (false point). The method of doing is similar to the acupressure group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals affiliated to Tehran University of Medical Sciences including Amir Aalam

Full name of responsible person

Hassan Babamohamadi

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Sponsors / Funding sources

1

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Name of organization / entity

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable