Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparative effect of Peppermint (Mentha Piperita) with placebo on nausea, vomiting and anorexia in patients with breast cancer under chemotherapy

Protocol summary

Study aim
Determine effect of Peppermint on nausea, vomiting and anorexia in Patients with breast cancer under chemotherapy

Design
Controlled clinical trial with a parallel group design

Settings and conduct
This study will be carried out at Ayatullah Khansari Hospital in Arak. Samples will be selected from female patients with breast cancer under chemotherapy..

Participants/Inclusion and exclusion criteria
The inclusion criteria included: diagnosis of breast cancer breast cancer and satisfaction participate in the study. Exclusion criteria included: discontinuation from the study and allergic to peppermint.

Intervention groups
Group 1 (intervention): 40 drops of Peppermint every 8 hours plus 20 cc of water; 12 hours before and 48 hours after chemotherapy Group 2 (placebo): 40 drops of distilled water every 8 hours plus 20 cc of water; 12 hours before and 48 hours after chemotherapy

Main outcome variables
Nausea; Vomiting; Anorexia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130731014229N7**
Registration date: **2018-04-19, 1397/01/30**
Registration timing: **prospective**

Last update: **2018-04-19, 1397/01/30**
Update count: **0**

Registration date
2018-04-19, 1397/01/30

Registrant information

Name
Hadi Jafari manesh

Name of organization / entity
Arak University of Medical Science

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Iran (Islamic Republic of)

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+98 86 3417 3503

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2019-05-22, 1398/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative effect of Peppermint (Mentha Piperita) with placebo on nausea, vomiting and anorexia in patients with breast cancer under chemotherapy

Public title
Effect of Peppermint on nausea, vomiting and anorexia in patients with breast cancer under chemotherapy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Satisfaction to participate in the study Diagnosis of

breast cancer History of receiving a chemotherapy course Experience nausea following previous chemotherapy

Exclusion criteria:

Unwillingness to continue participating in the study Forgetting the use of Peppermint in three times

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are randomly assigned to quadruple blocks A, A, B, B in random groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and data analyzer do not know which groups are located. The samples in the intervention and control group did not know whether they received the placebo or the main drug. The statistician will receive questionnaires as anonymously and in form A and B, and he does not know which are intervention and control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Basij Sq.

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2018-02-20, 1396/12/01

Ethics committee reference number

IR.ARAKMU.REC.1396

Health conditions studied

1

Description of health condition studied

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Nausea

Timepoint

At the beginning of the study (before the intervention) and immediately, 24 and 48 hours after the end of the chemotherapy

Method of measurement

VAS scale

2

Description

Vomiting

Timepoint

At the beginning of the study (before the intervention) and immediately, 24 and 48 hours after the end of the chemotherapy

Method of measurement

Frequency table

3

Description

Anorexia

Timepoint

At the beginning of the study (before the intervention) and immediately, 24 and 48 hours after the end of the chemotherapy

Method of measurement

VAS Scale

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, in addition to the medications prescribed by the physician, will be given 40 drops of peppermint of Barij Essence Company plus 20 cc of water every 8 hours, 12 hours before and 48 hours after

the Chemotherapy,

Category
Prevention

2

Description
Control group: For control group will be used normal saline as a placebo.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Khansari hospital

Full name of responsible person
Hadi Jafarianesh

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Daneshgah Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Mohammad Arjomandzadegan

Street address
Deputy of Research and Technology, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Hadi Jafarimanesh

Position
Faculty

Latest degree
Master

Other areas of specialty/work
Nursery

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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
No more information
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