Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of ginger (zingiber officinale) on the nausea and vomiting induced by cancer chemotherapy.

Protocol summary

Summary

The aim of this study is to determine the antiemetic effect of ginger on nausea and vomiting induced by chemotherapy drugs. This study is a phase II randomized, double-blind, placebo-controlled trial that will be conducted in cancer institute of Imam khomeini hospital, Tehran, Iran. 80 women with breast cancer (including 40 patients in the ginger and 40 in the placebo group), receiving chemotherapy will receive 1 gram of ginger root powder or placebo (lactose) orally/day (250mg capsule every 6h) for six days, starting three days before and ending three days after chemotherapy session. During this period, severity and number of nausea and vomiting episodes will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811203319N1**
Registration date: **2009-07-23, 1388/05/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-07-23, 1388/05/01

Registrant information

Name

Seyyed Meisam Ebrahimi

Name of organization / entity

Nursing & Midwifery College, Tehran University of Medical Sciences & Health Services

Country

Iran (Islamic Republic of)

Phone

00982166927171

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Recruitment status

Recruitment complete

Funding source

Tehran university of Medical Sciences

Expected recruitment start date

2009-07-23, 1388/05/01

Expected recruitment end date

2009-12-21, 1388/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ginger (zingiber officinale) on the nausea and vomiting induced by cancer chemotherapy.

Public title

Effect of ginger on chemotherapy induced nausea and vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of with breast cancer definite diagnosis by a pathologist, age more than 18 years, receiving chemotherapy, having at least one chemotherapy session before, having history of nausea and vomiting after chemotherapy, having one-day chemotherapy sessions Exclusion criteria: multi-days chemotherapy sessions, simultaneous radiotherapy inducing nausea and vomiting such as whole body or upper abdomen RT, consuming warfarin and heparin for treatment, consuming ASA more than 80mg, receiving heparin (except for iv-lines), history of blood discrasies, history of severe thrombocytopenia, allergy to ginger or consuming during the past week, gastro-intestinal

cancers, having other nausea and vomiting inducing factors except chemotherapy such as CNS tumors, HTN, renal failure or hepatic disorders, gastrointestinal problems like gastric or peptic ulcers, forgetting the use of capsules 3consecutive times or more

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Tehran University of Medical Sciences and Health Services

Street address
6th Floor, Central Organization, Next to Qods St., Keshavarz Boulevard

City
Tehran

Postal code

Approval date
empty

Ethics committee reference number
909/130/88/ص

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
Nausea severity

Timepoint
Data are recorded daily for six days (starting 3days before chemotherapy session).

Method of measurement
A 10 centimeter visual analogue scale (VAS)

2

Description
Number of Nausea episodes

Timepoint
Data are recorded daily for six days (starting 3days before chemotherapy session).

Method of measurement
Questionnaire

3

Description
Number of Vomiting episodes

Timepoint
Data are recorded daily for six days (starting from 3 days before chemotherapy session)

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Heart burn

Timepoint
Data are recorded daily for six days (starting 3 days before chemotherapy session).

Method of measurement
Questionnaire

Intervention groups

1

Description
Capsules of 250mg lactose are used qid (1g/day) for six days. placebo capsules are equal to ginger capsuls according to color, odor, taste, shape and dosage.

Category
Placebo

2

Description
Capsules of 250mg ginger powder are used qid (1g/day) for six days. Ginger capsules are equal to placebo capsuls according to color, odor, taste, shape and dosage.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Cancer Institute
Full name of responsible person
Dr. Sanambar Sadighi
Street address
Cancer Institute Central 2, Dr. Gharib St,
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Vice-chancellor, Tehran University of Medical Sciences and Health Services
Full name of responsible person
Dr. Fotohi
Street address
6th Floor, Central Organization, Next to Qods St., Keshavarz Boulevard
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Vice-chancellor, Tehran University of Medical Sciences and Health Services
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Nursing and Midwifery College, Tehran University of Medical Sciences and Health Services
Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty