

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Email address

sm_ebrahimi@razi.tums.ac.ir

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 address6th 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 sourceResearch 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**

Dr. Zohreh parsa yekta

Position

Associate professor

Other areas of specialty/work**Street address**3rd Floor, Nursing Department, Nursing and Midwifery
College, East Nosrat St., Tohid Sq.**City**

Tehran

Postal code**Phone**

00982166927171

Fax**Email**

zparsa@sina.tums.ac.ir

Web page address**Person responsible for scientific
inquiries****Contact****Name of organization / entity**Nursing and Midwifery College, Tehran University of
Medical Sciences and Health Services**Full name of responsible person**

Seyyed Meisam Ebrahimi

Position

Msc

Other areas of specialty/work**Street address**3rd Floor, Nursing Department, Nursing and Midwifery
College, East Nosrat St., Tohid Sq.**City**

Tehran

Postal code**Phone**

+98 24 2522 6900

Fax**Email**

sm_ebrahimi@razi.tums.ac.ir

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

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Other areas of specialty/work**Street address**3rd Floor, Nursing Department, Nursing and Midwifery
College, East Nosrat St., Tohid Sq.**City**

Tehran

Postal code**Phone****Fax****Email**

sm_ebrahimi@razi.tums.ac.ir

Web page address

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