Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of ginger and chamomile on nausea and vomiting caused by chemotherapy in women with breast cancer referred to the Breast cancer research centre, jahad daneshgahi in 2013

Protocol summary

Summary

The aim of this study was to compare the effect of ginger and chamomile on nausea and vomiting resulting from chemotherapy in (some) cancer patients. The study was a randomized triple blind clinical trial and conducted among 65 patients divided into three groups. Group of subject was randomly sampling selected from the breast cancer patients who receive chemotherapy at the Breast Cancer Research Center at the University of Medical Science one a month and complain of nausea, and the patients were also randomly assigned to two experimental groups and one control group. The experimental group 1 took 1 capsule of ginger besides the routine anti-nausea medication one hour before the chemotherapy, while the experimental group 2 took 1 capsule of Chamomile in the same condition. The control group takes only the routine anti-nausea medication dexamethasone and metoclopramide ampoules, and aprepitant capsule. The duration of experience was 5 days. For recording the frequency and severity of nausea and vomiting each member of three groups filled out the observation forms during this period. Each observation form contains two tables with a 10 cm visual analogue scale. At the end the results of the three groups are calculated and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020912404N1**
Registration date: **2015-03-14, 1393/12/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-03-14, 1393/12/23

Registrant information

Name

Fateme Sanaati

Name of organization / entity

Welfare and Rehabilitation Sciences University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Vice-chancellor, Welfare and Rehabilitation Sciences University of Medical Sciences

Expected recruitment start date

2013-05-06, 1392/02/16

Expected recruitment end date

2014-01-06, 1392/10/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of ginger and chamomile on nausea and vomiting caused by chemotherapy in women with breast cancer referred to the Breast cancer research centre, jahad daneshgahi in 2013

Public title

Effect of ginger and chamomile on nausea and vomiting

caused by chemotherapy Comparing the effect of ginger and chamomile on nausea and vomiting caused by chemotherapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Presence of with breast cancer definite diagnosis by a pathologist؛ age between 20 and 60 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 and chamomile 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

From **20 years** old to **60 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Welfare and Rehabilitation Sciences University of Medical Sciences

Street address

Kudakyar Avenue, Student Blvd, Evin, Tehran

City

Tehran

Postal code

1985713834

Approval date

2012-11-28, 1391/09/08

Ethics committee reference number

14126

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

For five days (from one hour before until five days after chemotherapy)

Method of measurement

A 10 centimeter visual analogue scale (VAS)

2

Description

Number of Nausea episodes

Timepoint

For five days (from one hour before until five days after chemotherapy)

Method of measurement

Questionnaire

3

Description

Number of Vomiting episodes

Timepoint

For five days (from one hour before until five days after chemotherapy)

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 hour for 5 days before and 5 days after chemotherapy, 2 times a day and 500 mg capsules

of powdered ginger root in addition to routine antiemetic regimen consisting of dexamethasone and metoclopramide and Aprepitant capsule was consumed

Category

Treatment - Drugs

2

Description

Intervention group 1 hour for 5 days before and 5 days after chemotherapy, 2 times a day and 500 mg capsules of Matricaria Chamomilla extract in addition to routine antiemetic regimen consisting of dexamethasone and metoclopramide and Aprepitant capsule was consumed

Category

Treatment - Drugs

3

Description

Control group, routine antiemetic regimen consisting of dexamethasone and metoclopramide and Aprepitant capsule was consumed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Breast Cancer Research Center, Tehran University of Medical Sciences SID

Full name of responsible person

Dr. Safa Najafi

Street address

martyr St. Vahid Nazari, University Street, Enghelab Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice-chancellor, Welfare and Rehabilitation Sciences University of Medical Sciences

Full name of responsible person

Dr.Hasan Shakeri

Street address

Kudakyar Avenue, Student Blvd, Evin, Tehran

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, Welfare and Rehabilitation Sciences University of Medical Sciences

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

Welfare and Rehabilitation Sciences University of Medical Sciences

Full name of responsible person

Dr.Zahra Kashaninia

Position

Faculty of Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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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