

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the effect of combined ginger and quince on dyspepsia in cancer patients undergoing concurrent chemotherapy and radiotherapy

Protocol summary

Summary

Objectives: this study is aimed to determine the effect of the ginger-quince compound on dyspepsia of cancerous patients under chemotherapy and radiotherapy treatments at the same time . This study is a Phase 3 clinical trial; a double blind, randomized, and controlled trial with placebo. Method: inclusion criteria: suffering from cancer; definitely diagnosed by a pathologist; age, 18 year-old or more; under chemotherapy treatments; simultaneous radiotherapy treatments inducing nausea and vomiting such as whole body or upper abdomen RT. Exclusion criteria: Warfarin and Heparin treatment; ASA consuming more than 80 mg; history of blood disorders; history of severe thrombocytopenia; allergy to ginger or consuming it during the past week; gastro-intestinal cancers; having nausea and vomiting induced by factors except chemotherapy or radiotherapy such as CNS tumors, HTN, renal failure or hepatic disorders; gastrointestinal problems like gastric or peptic ulcers; forgetting the use of capsules three consecutive times or more. Intervention: randomized prescription of standard ginger and quince capsules or placebo three times a day, within 15 minutes of each meal , both starting from 3 days before chemotherapy until completion of radiotherapy period (six weeks). During treatment, the routine anti-vomiting protocol for all patients will be prescribed Main outcome measures : guring this period nausea , vomiting , bloating , anorexia , poor appetite and postprandial fullness following chemotherapy and radiotherapy will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111815436N1**

Registration date: **2014-12-29, 1393/10/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-29, 1393/10/08

Registrant information

Name

Mahdiye Falamarzi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6640 4377

Email address

hosp_cancer@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

1.Vice-chancellor for research, Tehran university of medical sciences and health services; 2.Simorgh-e-Hekmat knowledge-base institute

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of combined ginger and quince on dyspepsia in cancer patients undergoing concurrent chemotherapy and radiotherapy

Public title

The effect of ginger-quince compound on dyspepsia

induced by chemotherapy and radiotherapy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: suffering from cancer; definitely diagnosed by a pathologist; 18 year-old or more; under chemotherapy treatments; simultaneous radiotherapy treatments inducing nausea and vomiting such as whole body or upper abdomen. Exclusion criteria: Warfarin and Heparin treatment; ASA consuming more than 80 mg; history of blood disorders; history of severe thrombocytopenia; allergy to ginger or consuming it during the past week; gastro-intestinal cancers; having nausea and vomiting induced by factors except chemotherapy or radiotherapy such as CNS tumors, HTN, renal failure or hepatic disorders; gastrointestinal problems like gastric or peptic ulcers; forgetting the use of capsules three consecutive times or more.

Age
From **18 years** old to **139 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

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

floor 6, Central organization of university, Next to Qods St, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2012-12-03, 1391/09/13

Ethics committee reference number

2136/130/91/3

Health conditions studied

1

Description of health condition studied

dyspepsia

ICD-10 code

F45.3

ICD-10 code description

Somatoform autonomic dysfunction

Primary outcomes

1

Description

Nausea

Timepoint

During the intervention, weekly

Method of measurement

Data registration form

2

Description

vomiting

Timepoint

During the intervention, weekly

Method of measurement

Data registration form

3

Description

bloating

Timepoint

During the intervention, weekly

Method of measurement

Data registration form

4

Description

anorexia

Timepoint

During the intervention, weekly

Method of measurement

Data registration form

5

Description

poor appetite

Timepoint

During the intervention, weekly

Method of measurement

Data registration form

6

Description

postprandial fullness

Timepoint

During the intervention, weekly

Method of measurement

Data registration form

Secondary outcomes

empty

Intervention groups

1

Description

Cases is prescribed standardized ginger and quince capsules three times a day, within 15 minutes of each meal, starting from 3 days before chemotherapy until completion of radiotherapy period (six weeks)

Category

Treatment - Drugs

2

Description

Control group is prescribed placebo (lactose- bran compound) three times a day, within 15 minutes of each meal, starting from 3 days before chemotherapy until completion of radiotherapy period (six weeks)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute of Imam Khomeini hospital

Full name of responsible person

Dr Ali Kazemian

Street address

Imam Khomeini hospital complex , Keshavarz Blvd

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Simorgh-e-Hekmat knowledge-base institute

Full name of responsible person

Dr Hossein Rezaeizade

Street address

Unit 3, Issue 4, Gity Alley, Next to the Toloe pharmacy, Keshavarz Blvd, North Kargar St

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Simorgh-e-Hekmat knowledge-base institute

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Research vice-chancellor, Tehran university of medical sciences and health services

Full name of responsible person

Dr Masud Yunesian

Street address

floor 6, Central organization of university, Next to Qods St, Keshavarz Blvd

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

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

Medicin college, Tehran university of medical sciences and health services

Full name of responsible person

Mahdiyeh Falamarzi

Position

Medical student

Other areas of specialty/work

Street address

No 1, North door of Tehran university, Poursina St, Ghods St, Enghelab St

City

Tehran

Postal code
Phone
+98 21 6640 4377
Fax
Email
mhdyl227@gmail.com , m.falamarzi313@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran university of medical sciences and health services, Cancer research center (Cancer Institute)

Full name of responsible person

Dr Ali Kazemian

Position

Associate professor

Other areas of specialty/work

Street address

Imam Khomeini hospital complex, Keshavarz Blvd

City

Tehran

Postal code

Phone

+98 21 6658 1571

Fax

Email

kazemian@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Medicine college, Tehran university of medical sciences and health services

Full name of responsible person

Mahdiyeh Falamarzi

Position

Medical students

Other areas of specialty/work

Street address

No 1, North door of Tehran university, Poursina St, Ghods St, Enghelab St

City

Tehran

Postal code

Phone

00

Fax

Email

mhdyl227@gmail.com , m.falamarzi313@yahoo.com

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