Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of ginger and cinnamon in comparison with control group, on chemotherapy induced nausea and vomiting with high emetic drugs in cancer patients

Protocol summary

Study aim
The effect of ginger and cinnamon on chemotherapy induced nausea and vomiting

Design
Randomised, sham controlled, parallel group clinical trial, phase 3 on 144 patients with double blinded outcome assessment. Randomisation was done based on restricted randomization and we will use random allocation rule and numbered drug containers.

Settings and conduct
The target population of this study is cancer patients undergoing chemotherapy in medical centers affiliated to Isfahan University of Medical Sciences.The effect of cinnamon and ginger combination on nausea is assessed with a questionnaire. The drugs are coded by a pharmacotherapist so that all those involved in the research are unaware of the true nature of the capsules and only the analyzer will be informed at the time of analysis.

Participants/Inclusion and exclusion criteria
Inclusion criteria are : Age 18 years and older Definitive diagnosis of cancer Receive one-day chemotherapy courses with high emetic risk drugs Normal hematological and biochemical tests The following are exclusion criteria: Receiving concurrent radiotherapy with chemotherapy Taking therapeutic doses of warfarin, heparin or aspirin History of hematological disorders Gastrointestinal cancer History of allergy to ginger or cinnamon Taking ginger or cinnamon during the last week Having other problems causing nausea

Intervention groups
Intervention group is treated with capsules containing Ginger and Cinnamon and the control group takes placebo. The intervention is performed for six days, starting from 3 days before chemotherapy and during this period, in addition to the usual regimens that include Granisetron Hydrochloride and Dexamethasone, the intervention group takes capsules as a supplement every 6 hours, and similarly the control group takes placebo.

Main outcome variables
Nausea severity; Vomiting severity; Nausea frequency; Vomiting frequency

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201123049474N1**
Registration date: **2020-11-27, 1399/09/07**
Registration timing: **prospective**

Last update: **2020-11-27, 1399/09/07**
Update count: **0**

Registration date
2020-11-27, 1399/09/07

Registrant information

Name
Mohammad Amin

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 3781 2884

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-20, 1399/09/30

Expected recruitment end date
2021-06-20, 1400/03/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of ginger and cinnamon in comparison with control group, on chemotherapy induced nausea and vomiting with high emetic drugs in cancer patients

Public title
The effect of ginger and cinnamon on chemotherapy induced nausea and vomiting
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years and older Definitive diagnosis of cancer by oncologist and pathologist Receive one-day chemotherapy courses with high emetic risk drugs according to the American Society of Clinical Oncology Guidline Normal hematological and biochemical tests
Exclusion criteria:
Receiving concurrent radiotherapy with chemotherapy Taking therapeutic doses of warfarin, heparin or aspirin History of hematological disorders (such as severe thrombocytopenia) Gastrointestinal cancer History of allergy to ginger or cinnamon Taking ginger or cinnamon during the last week Having other problems causing nausea such as hypertension, liver or kidney failure and digestive problems
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **144**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done with a simple random method and creating random values between zero and one in spss software. In order to determine random values to the intervention or control group, less than or equal to 0.5 values are assigned to group A and values greater than 0.5 to group B. The pharmacotherapist then encodes 144 packages (based on the codes obtained in the above randomization method) and determines the list of codes. Inside each package, according to the above method, intervention medicine or placebo will be placed and in order of eligible patients entering the clinic, will be given to the patients and the method of taking the drugs will be explained to the patients by oncologist. Package codes are written on each patient's questionnaire.
Blinding (investigator's opinion)
Double blinded
Blinding description
Drugs and placebo are prepared by pharmacotherapist in similar shapes, colors and weights and are packaged and coded in similar packages in two groups of drugs and placebo so that all people involved in the research are unaware of the main nature of the capsules. After collecting the data, an envelope related to the coding of drug packages and patient information will be provided to the data analyzer.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan medical university
Street address
Ethics committee of Isfahan medical university, Building No. 4, Isfahan medical university, Hezar Jarib Street
City
Isfehan
Province
Isfehan
Postal code
8174673461
Approval date
2020-11-24, 1399/09/04
Ethics committee reference number
IR.MUI.MED.REC.1399.753

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

Frequency of nausea and vomiting

Timepoint

3 days before chemotherapy to 3 days after and every 12 hours at the same time as the intervention

Method of measurement

The Index of Nausea, Vomiting, and Retching questionnaire

2

Description

Intensity of nausea and vomiting

Timepoint

3 days before chemotherapy to 3 days after and every 12 hours at the same time as the intervention

Method of measurement

The Index of Nausea, Vomiting, and Retching questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Capsules containing 250 mg of Ginger and 250 mg of Cinnamon, which is taken every 6 hours from 3 days before the start of chemotherapy to 3 days after and produced by Amin Pharmaceutical Company

Category

Prevention

2

Description

Control group: Placebo is similar in weight and appearance to the intervention drug produced by Amin Pharmaceutical Company

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Mohammad Amin

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Soffe Blvd, Shahid Keshvari High Way

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Recruitment center

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3

Recruitment center

Name of recruitment center

Sheikh Mofid Clinic

Full name of responsible person

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Mohamad606@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghaiegh Haghjoo Javanmard

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Vice Chancellery for Research and Technology of Isfahan medical university, Building No. 4, Isfahan medical university, Hezar Jarib Street

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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Amin
Position
Resident
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected deidentified IPD

When the data will become available and for how long

6 months after publication

To whom data/document is available

academic institutions

Under which criteria data/document could be used

Any analysis is allowed

From where data/document is obtainable

Email address: Mohammad Amin
dr.mohamad.amin@gmail.com

What processes are involved for a request to access data/document

Send the request and the type of data analysis used to the relevant email for review

Comments