Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of ginger in control of nausea and vomiting in cancer patients receiving doxorubicin and platinum based chemotherapy

Protocol summary

Study aim
Reducing the frequency and severity of nausea and vomiting in cancer patients

Design
A clinical trial study with a control group with cross-over groups, double-blind, block randomized and phase 3 on 44 cancer patients

Settings and conduct
Ginger and placebo capsules are given to the patient by the nurse in the hospital for 24 hours; The capsule is then taken by the patient. Blinding is done by coded boxes and the wash out period is equivalent to the interval between two cycles of chemotherapy (about one month).

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Age over 18 years 2. Prescribing chemotherapy regimen based on doxorubicin and platinum compounds by the oncologist 3. Ability to swallow capsules 4. Having chemotherapy experience with nausea and vomiting 5. Presence in the ward for 24 hours to evaluate anti-nausea drugs 6. No history of nausea and vomiting for reasons other than chemotherapy 7. Not receiving anti nausea and vomiting drugs in the last 24 hours Exclusion criteria: 1. Patients who do not sign the moral consent form. 2. Patients who do not cooperate during treatment for any reason. 3. History of any allergy to ginger 4. Occurrence of nausea before chemotherapy for any reason 5. Having any disease that causes nausea and vomiting, such as hepatitis, gastrointestinal obstruction 6. Taking anticoagulants such as heparin 7. The presence of blood disorders such as platelets less than 10,000 per µl

Intervention groups
The intervention group is the group of patients receiving ginger capsules and the control group is the group of patients receiving placebo capsules; We give the first capsule half an hour before chemotherapy and then every 8 hours for 5 days.

Main outcome variables
The severity and frequency of acute and delayed nausea; The severity and frequency of acute and delayed vomiting.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210505051188N1**
Registration date: **2021-06-25, 1400/04/04**
Registration timing: **prospective**

Last update: **2021-11-15, 1400/08/24**
Update count: **1**

Registration date
2021-06-25, 1400/04/04

Registrant information

Name
Ali Adineh kharrat

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4413 7601

Email address
amirali.adn96@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-11, 1400/04/20

Expected recruitment end date
2022-01-10, 1400/10/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ginger in control of nausea and vomiting in cancer patients receiving doxorubicin and platinum based chemotherapy

Public title

The effect of ginger on the severity and frequency of chemotherapy-induced nausea and vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Prescribing chemotherapy regimen based on doxorubicin and platinum compounds by the oncologist Ability to swallow capsules Having chemotherapy experience with nausea and vomiting Presence in the ward for 24 hours to evaluate anti-nausea drugs No history of nausea and vomiting for reasons other than chemotherapy Not receiving anti-nausea and vomiting drugs in the last 24 hours

Exclusion criteria:

Patients who do not sign the moral consent form. Patients who do not cooperate during treatment for any reason to continue treatment. History of any allergy to ginger Occurrence of nausea before chemotherapy for any reason Having any disease that causes nausea and vomiting, such as hepatitis, gastrointestinal obstruction Taking anticoagulants such as heparin The presence of blood disorders such as platelets less than 10,000 per microliter.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization; Random assignment of participants to a number of fixed capacity blocks in which half of the individuals are assigned to the control group and the other half to the intervention group. The randomization method in this study is to shuffle the cards; In this method, a number of cards selected by the researcher as the first group and the same number of cards for the next groups are considered; Then, by merging the cards together (shuffling the cards), a card is removed and its group is recorded; Coded boxes containing the drug are also used to hide randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind a) patients b) Oncologist and nurse

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences (Biomedical Research Ethics Committee)

Street address

Ahvaz Jondi Shapor university of medical sciences,Esfand Ave,Farvardin Blvd,Golestan

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Approval date

2021-05-01, 1400/02/11

Ethics committee reference number

IR.AJUMS.REC.1400.074

Health conditions studied

1

Description of health condition studied

Chemotherapy induced nausea and vomiting

ICD-10 code

T45.1X5A

ICD-10 code description

Adverse effect of antineoplastic and immunosuppressive drugs

Primary outcomes

1

Description

Frequency of acute and delayed nausea

Timepoint

Frequency of patient nausea up to 24 hours after chemotherapy for acute nausea and frequency of patients nausea p from 24 hours after chemotherapy to 4 days for delayed nausea

Method of measurement

Asking the patient

2

Description
Frequency of acute and delayed vomiting
Timepoint
Frequency of patient vomiting up to 24 hours after chemotherapy for acute vomiting and frequency of patients vomiting from 24 hours after chemotherapy to 4 days for delayed vomiting
Method of measurement
Asking the patient

3

Description
Severity of acute and delayed nausea
Timepoint
Severity of patient nausea up to 24 hours after chemotherapy for acute nausea and severity of patients nausea from 24 hours after chemotherapy to 4 days for delayed nausea
Method of measurement
Stepwise method that is taught to the patient.In this method, the base level is equal to the absence of nausea, steps 1 to 3 is equal to mild nausea, steps 4 to 6 is equal to moderate nausea, steps 7 to 9 is equal to severe nausea and step 10 is the most severe nausea possible.

4

Description
Severity of acute and delayed vomiting
Timepoint
Severity of patient vomiting up to 24 hours after chemotherapy for acute vomiting and severity of patients vomiting from 24 hours after chemotherapy to 4 days for delayed vomiting
Method of measurement
Stepwise method that is taught to the patient.In this method, the base level is equal to the absence of nausea, steps 1 to 3 is equal to mild nausea, steps 4 to 6 is equal to moderate nausea, steps 7 to 9 is equal to severe nausea and step 10 is the most severe nausea possible.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: The group receiving the placebo is that the treatment regimen consists of standard antiemetic and vomiting drugs, including 1 ampoule of granistron (Kytril) 3 mg, 1 ampoule of dexamethasone 8 mg, one capsule of 125 mg, and 2 capsules of 80 mg of aprepitant. Placebo capsules (containing starch), so that the patient will receive 1 capsule 30 minutes before taking oral chemotherapy drugs and other capsules every 8 hours for 5 days after chemotherapy.
Category
Treatment - Drugs

2

Description
Intervention group: The intervention group is the drug receiving group whose treatment regimen consists of standard antiemetic and vomiting drugs including 1 ampoule of granistron (kytril) 3 mg and 1 ampoule of dexamethasone 8 mg and one capsule of 125 mg and 2 capsules of 80 mg of aprepitant with 500 mg ginger capsule, so that the patient will receive 1 capsule 30 minutes before taking chemotherapy drugs, orally and other capsules every 8 hours for 5 days after chemotherapy
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
Mohamadjavad Khodayar
Street address
Golestan Hospital, Farvardin Blvd., Golestan
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohamadjavad Khodayar
Street address
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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

MohamadJavad Khodayar

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Toxicology

Street address

Department of Toxicology,Faculty of Pharmacy,Ahvaz Jondi Shapor university of medical sciences,Esfand Ave,Farvardin Blvd,Golestan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

MohamadJavad Khodayar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Toxicology

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Ali Adineh-Kharrat

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Faculty of Pharmacy,Ahvaz Jondi Shapor university of medical sciences,Esfand Ave,Farvardin Blvd,Golestan

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not 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

Research data can be presented if individuals are not identified.

When the data will become available and for how long

It will be available forever for another 8 months when the research and publication of the manuscript is completed.

To whom data/document is available

It will be available to the public.

Under which criteria data/document could be used

The data can be used for further research and studies and by an article extracted from the research.

From where data/document is obtainable

The data will be published in the form of an article and will be available via the following email in case of further details. jkhodayar@yahoo.com khodayar-mj@ajums.ac.ir

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

No special process is required and will be available via email upon request.

Comments