Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness of Galenos Barij Syrup on preventing nausea and vomiting in patients referred to outpatient chemotherapy receiving the regime with high emetic chemotherapy (HEC) compared to the standard regime

Protocol summary

Study aim

Evaluating the effectiveness of Galenos barrage syrup with standard treatments to prevent chemotherapy-induced nausea and vomiting (CINV) in patients receiving highly emetogenic chemotherapy (HEC) based on Rhodes Index and NRS score Identification of different side effects of Galenos barrage syrup in patients treated with highly emetogenic chemotherapy (HEC) regimens

Design

This is a multicenter, controlled, parallel-group, unblended, randomized, phase III, and clinical trial on 56 patients. Block randomization was used to reduce bias in trial.

Settings and conduct

Patients admitted to the Tooba clinic and Imam Khomeini Hospital in Sari were included based on inclusion and exclusion criteria and randomly assigned to two separate (intervention and control) groups. The intervention group will receive the combination of standard antiemetic therapy plus chemotherapy and control group will receive standard antiemetic therapy (aprepitant, granisetron, and dexamethasone).

Participants/Inclusion and exclusion criteria

Inclusion criteria Patients ≥ 18 years old receiving high emetogenic chemotherapeutic agents Exclusion criteria Patients who have known allergy or severe side effect on Ginger consuming Ginger within a week before the intervention receiving warfarin, heparin, and aspirin Patients with a history of a neurological disorder, seizures and epilepsy, hematologic diseases Patients with GI obstruction, brain and/or GI metastasis Patients who lack capacity to consent to research

Intervention groups

Intervention: In addition to standard antiemetic therapy, patients received Galenos barrage syrup 5-10 CC according to body weight before each meal on the same day as the chemotherapy regimen Control: Standard antiemetic therapy (aprepitant, granisetron, and dexamethasone)

Main outcome variables

Nausea and vomiting based on Rhodes Index and NRS score and side effects of Galenos barrage syrup

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230807059069N1**
Registration date: **2023-10-24, 1402/08/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-24, 1402/08/02**
Update count: **0**

Registration date

2023-10-24, 1402/08/02

Registrant information

Name

Mohammad Mehdi Vaziri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Galenos Barij Syrup on preventing nausea and vomiting in patients referred to outpatient chemotherapy receiving the regime with high emetic chemotherapy (HEC) compared to the standard regime

Public title

The effect of Galenos Barij Syrup on nausea and vomiting caused by chemotherapy with strong emetic ability compared to standard treatment.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

People over the age of 18 Patients under high emetogenic chemotherapy regimens (HEC) referring to outpatient chemotherapy at Imam Khomeini Hospital and Baghban Complex

Exclusion criteria:

Allergy to ginger Ginger consumption within a week before the start of the intervention Users of warfarin, heparin and aspirin drugs History of neurological diseases, history of seizures and epilepsy, history of blood disorders Patients with bowel obstruction or brain or bowel metastasis Lack of consent to participate in the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done by block method (Randomization Block) with a block size of four and using Sealed Envelope online software at the address https://www.sealedenvelope.com at an individual level and by an epidemiologist researcher who is a member of the research team. In this site, which is an online software for creating random allocation, the create list option is selected through the randomization menu, and then the required parameters such as groups A and B, the number of blocks, which is 4, and the total number of samples will be entered. And finally the random allocation list will be created. A sealed non-transparent envelope will be used for concealment. Researchers enroll eligible participants after the baseline assessment, then remove and open each envelope in the order that corresponds to the participant's initial assessment order, and assign the eligible participant to either the intervention group or the control group.

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

Imam (RA) Sari Educational and Medical Hospital - Mazandaran University of Medical Sciences (Researc

Street address

Imam Khomeini Hospital, Razi St.

City

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Province

Mazandaran

Postal code

4816633131

Approval date

2022-07-10, 1401/04/19

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1402.044

Health conditions studied

1

Description of health condition studied

Chemotherapy

ICD-10 code

Z51.1

ICD-10 code description

Encounter for Antineoplastic Chemotherapy and Immunotherapy

Primary outcomes

1

Description

The Rhodes Index questionnaire will evaluate the main outcome of the study. This tool (Nausea and Vomiting Index) is designed as a 5-point Likert scale (score 0-4). The final score range will vary between 0-32. In order to interpret the scores obtained from the questionnaire, the

average scores related to nausea and vomiting in each group were calculated. The Rhodes questionnaire will be completed daily.All patients were provided with a daily side effect checklist at the first visit to the outpatient chemotherapy clinic. Using the checklist, patients will record daily their nausea with a numerical rating scale (NRS) (0-10) and the number of times or episodes of vomiting up to 7 days after chemotherapy. The physician implementing the plan will record the amount of control of nausea and vomiting in the medical record after confirming the data or hearing the results of the patients at the next visit. Complete protection from nausea (NRS <1) and vomiting (no episodes) during the acute (within 24 hours after chemotherapy) and delayed (within 2 to 7 days after chemotherapy) episodes in patients receiving the first cycle of chemotherapy or will be evaluated in general cycles of chemotherapy.

Timepoint

Patients will record daily nausea (0-10) and the number of times or episodes of vomiting up to 7 days after chemotherapy.

Method of measurement

Rhodes Index Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In our current study, we used 5-10 cc barrage syrup based on person weight. Barrage syrup is containing fruit (Cydonia oblonga), ginger (Zingiberofficinale), vinegar and honey as an adjunctive treatment to the standard treatment containing a 5-HT3R inhibitor (Granicitron (Kytril brand)), NK1 receptor antagonist (We will use aperpitant (amand brand name) and dexamethasone.The anti-nausea effect of this product is on the one hand due to the presence of "Bah" fruit extract and on the other hand due to the presence of ginger. It becomes natural. Also, consuming "beh" after meals helps to eliminate indigestion and improve the digestive condition.Natural honey has antimicrobial and antibacterial properties and other enzymes that produce a small amount of hydrogen peroxide. Hydrogen peroxide, in turn, relieves you of indigestion. Natural honey contains the enzymes invertase, catalase, peroxidase, glucose oxidase, phosphatase and enolase acid, which help in proper digestion. It also contains potassium, which relieves nausea and inflammation of the lining of the esophagus and helps the stomach to neutralize acids. Honey is anti-nausea, and regular consumption of honey affects the muscles of the stomach and helps with proper digestion. . Also, natural honey stabilizes the content of hydrochloric acid in the body.Being rich in some vitamins, vinegar is very effective in the health of the digestive system and its elimination of toxins. It also has a significant effect in the treatment of some diseases and disorders of the digestive system, such as better digestion of food and reduction of nausea.

Category

Treatment - Drugs

2

Description

Control group: According to the clinical guidelines for the prevention of CINV in people undergoing chemotherapy with a high risk of emesis (HEC), a combination of 5-HT3 receptor antagonist (Granicitron 3 mg), NK-1 receptor antagonist (Aprepitant 125 mg daily) and dexamethasone 8 mg will be used as the standard before chemotherapy and a combination of aprepitant and dexamethasone will be given on days 2 and 3 and dexamethasone on day 4.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Mohammad Mehdi Vaziri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Vice President of Research and Technology(Dr. Pedram Ebrahimnejad)

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Taleghani Boulevard, Moalem Street, Moalem Square

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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
Mazandaran 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
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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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only a part of the data, such as the information related to the main result or the like, can be shared.
When the data will become available and for how long

Since 2025

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

There are no other conditions for the use of data or documentation. No analysis is allowed on the delivered data.

From where data/document is obtainable

MOHAMMAD MEHDI VAZIRI drmmvaziri@gmail.com

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

After communicating through the above email, the desired request will be submitted

Comments