

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Effect of Adding Ginger to Current Treatment on the Intensity of Nausea and Vomiting in Cancer Chemotherapy

#### Protocol summary

##### Summary

Introduction: nausea and vomiting caused by chemotherapy is the most important complication and discomfort for cancer patients. Nausea and vomiting causes physiologic and electrolyte disorders, Immunity system changes, Nutrition disorders and rupture of esophagus and effect in the quality of life and continuing of patients treatment. Ginger is one vegetable and effective drug for the treatment of nausea and vomiting and doesn't have any special side effects and some countries use it to produce antiemetic drugs. Objective : This study aims to determine the effect of ginger on the severity of chemotherapy induced nausea and vomiting in cancer patients. Material and Methods: This study is a randomized, cross-over, double - blinded, clinical trial, done on 44 cancer patients undergoing chemotherapy. In the first cycle of the study, Patients randomly assigned by four block random allocation to receive one of the antiemetic regimen (regimen A (routine + 1 gr ginger ) and regimen B(routine +1gr Placebos). In the next cycle of chemotherapy , 28 days after the previous cycle another regimen (A or B ) administrated together with chemotherapy drugs. The severity of the nausea and vomiting were measured in 4h (1,2,3,4 (hours) after second dose and at the end of the 24h after receiving first dose by using of VAS and kortila tools . Key word: Drug Therapy/ Ginger/ Nausea/ Neoplasms/ Oncologic Nursing/ Vomiting

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138706111174N1**

Registration date: **2010-12-29, 1389/10/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-12-29, 1389/10/08

##### Registrant information

###### Name

Atefeh Ghanbari

###### Name of organization / entity

Guilan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13780509

###### Email address

at\_ghanbari@gums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Guilan University of Medical Sciences

##### Expected recruitment start date

2007-08-23, 1386/06/01

##### Expected recruitment end date

2008-02-20, 1386/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Adding Ginger to Current Treatment on the Intensity of Nausea and Vomiting in Cancer Chemotherapy

##### Public title

Effects of ginger on Nausea and vomiting

##### Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: age more than 18 years old, having experience of chemotherapy along with nausea and vomit, having minimum two chemotherapy periods containing of 50-100 milligram per square meter of sys-platinum, individually or along with other factors of chemotherapy with the similar amount and method of prescription in two chemotherapy cycles without any plan for radiotherapy between two cycles, Remaining in the ward for a period of 24 hours (in order to study of the PRN anti-nausea drugs), Not having nausea and vomit for reasons other than chemotherapy, non-receiving anti-nausea and anti-vomit drugs during the past 24 hours, not receiving treatment with Corticosteroid Drugs during the studied cycles, not-suffering from Hepatitis, obstruction of digestion system, cerebral malignancy or cerebral metastasis and coagulation disorders (plaque less than 100000 per cubic millimeter) based on the registered information in the file and not consuming any anti-coagulation drug. Exclusion criteria: radiotherapy during research, severe nausea and vomiting, not able to eat capsule, stop chemotherapy for any reasons, sever gastroenteritis

### Age

From **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **44**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Crossover

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

##### Street address

Guilan , Rasht,Guilan University of Medical Sciences

##### City

Rasht

##### Postal code

0098

### Approval date

2007-07-25, 1386/05/03

### Ethics committee reference number

2256

## Health conditions studied

### 1

#### Description of health condition studied

neoplasm

#### ICD-10 code

coo-c97

#### ICD-10 code description

c97

## Primary outcomes

### 1

#### Description

nausae and vomiting

#### Timepoint

1, 2, 3, 4, 24 hours

#### Method of measurement

cheklist

## Secondary outcomes

### 1

#### Description

nausea and vomiting

#### Timepoint

28 days after first dose drugs , (change regime A,B) and after that for 1, 2,3,4 and 24 after that , nause and vomit was assessed

#### Method of measurement

cortilla tool

## Intervention groups

### 1

#### Description

In the first cycle of the study, patients received one of the antiemetic regimen, regimen A (routine + 1 gr ginger ) or regimen B (routine +1gr Placebos)

#### Category

Treatment - Drugs

### 2

#### Description

In the next cycle of chemotherapy , 28 days after the previous cycle another regimen (A or B ) administrated together with chemotherapy drugs

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Guilan University of Medical Sciences (hematology and cancer research center)

**Full name of responsible person**

Aefeh Ghanbari

**Street address**

Namjoo Street , Guilan University of Medical Sciences

**City**

Rasht

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

vice chancellor for research , Guilan University of Medical Sciences

**Full name of responsible person**

Dr Abdolrasoul Sobhani

**Street address**

Namjoo Street , Guilan University of Medical Sciences

**City**

Rasht

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

vice chancellor for research , Guilan 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**

Guilan University of Medical Sciences

**Full name of responsible person**

Atefeh Ghanbari

**Position**

PHD

**Other areas of specialty/work****Street address**

Rasht , Namjoo Street , Guilan University Of Medical Sciences

**City**

Rasht

**Postal code****Phone**

+98 13 1322 2071

**Fax**

+98 13 1555 0098

**Email**

at\_ghanbari@gums.ac.ir

**Web page address**

www.gums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Guilan University Of Medical Sciences

**Full name of responsible person**

Atefeh Ghanbari

**Position**

PHD

**Other areas of specialty/work****Street address**

Guilan University of Medical Sciences

**City**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Guilan University Of Medical Sciences

**Full name of responsible person**

Atefeh Ghanbari

**Position**

PHD

**Other areas of specialty/work****Street address**

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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*