Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study of the effects of apple (Malus domestica) syrup and barberry (Berberis orietalis) syrup on chemotherapy-induced nausea and vomiting

Protocol summary

Summary

This study will be performed as a double-blind, placebo-controlled clinical trial in Baghban Clinic of Mazandaran University of Medical Sciences on 60 patients with chemotherapy-induced nausea and vomiting. The patients experienced nausea and vomiting during the previous cycle of chemotherapy who received the same chemotherapy regime with previous chemotherapy cycle will be randomly enrolled in 3 groups containing of 20 patients to receive placebo, apple or barberry syrup. Due to the four-digit code for each syrup, patients in each group and their physicians will not be aware of the type of treatment which they will receive and the patients also will receive routine anti-emetic treatments along with the study drug. The objectives of the study is to reduce the chemotherapy-induced nausea and vomiting. The efficacy of the interventions on incidence and severity of nausea and vomiting will be recorded in the data collection form based on MASCC/ESMO Antiemetic Guidelines and compared with the appropriate statistical tests by SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709142027N10**
Registration date: **2017-09-27, 1396/07/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-27, 1396/07/05

Registrant information

Name

Ebrahim Salehifar

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 15 1311 6546

Email address

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effects of apple (Malus domestica) syrup and barberry (Berberis orietalis) syrup on chemotherapy-induced nausea and vomiting

Public title

study of the effects of apple syrup and barberry syrup on chemotherapy-induced nausea and vomiting

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The patients older than 18 years; with diagnosed cancer that experienced nausea and vomiting during the previous cycle of chemotherapy who received the same chemotherapy and anti-emetic regime with previous chemotherapy cycle at the time of enrollment in the study Exclusion criteria: Uncontrolled Diabetes

Mellitus; Changes in chemotherapy regime; Having other clinical conditions that cause nausea and vomiting such as brain metastasis.

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The eligible patients will be assigned to the treatments (apple and barberry syrup) or placebo groups by simple randomization as 1:1:1 ratio

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of mazandaran University of Medical Sciences

Street address
Moallem Square, Research Deputy of Mazandaran University of Medical Sciences

City
Sari

Postal code

Approval date
2017-04-04, 1396/01/15

Ethics committee reference number
IR.MAZUMS.REC.95.2254

Health conditions studied

1

Description of health condition studied
chemotherapy-induced nausea and vomiting

ICD-10 code
Y43.3

ICD-10 code description
Drugs, medicaments and biological substances causing adverse effects in therapeutic use

Primary outcomes

1

Description
Incidence of nausea

Timepoint
24 hours after chemotherapy

Method of measurement
Patients questionnaire based on MASCC/ESMO Antiemetic Guidelines

2

Description
Incidence of vomiting

Timepoint
24 hours after chemotherapy

Method of measurement
Patients questionnaire based on MASCC/ESMO Antiemetic Guidelines

Secondary outcomes

1

Description
Severity of nausea

Timepoint
1 day before chemotherapy to 6 days after chemotherapy

Method of measurement
Patients questionnaire based on MASCC/ESMO Antiemetic Guidelines

2

Description
Severity of vomiting

Timepoint
1 day before chemotherapy to 6 days after chemotherapy

Method of measurement
Patients questionnaire based on MASCC/ESMO Antiemetic Guidelines

Intervention groups

1

Description
barberry syrup 34.75% 1 day before chemotherapy to 6 days after chemotherapy, 10 ml of syrup Three times daily

Category
Treatment - Drugs

2

Description

Apple syrup 20% 1 day before chemotherapy to 6 days after chemotherapy, 10 ml of syrupTDS daily

Category

Treatment - Drugs

3

Description

Placebo syrup 1 day before chemotherapy to 6 days after chemotherapy, 10 ml of syrupTDS daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghban Clinic of Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Salehifar

Street address

Khazar Square

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Vice Chancellor for Research, Moalem square

City

Sari

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, Mazandaran 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

Faculty of Pharmacy, Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Salehifar

Position

Professor of Clinical Pharmacy

Other areas of specialty/work

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Person responsible for scientific inquiries

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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