

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation the effectiveness of a mixture-syrup based on pomegranate and spearmint (Vomigramint), compared with placebo, on Chemotherapy induced nausea and vomiting (CINV) in breast cancer

Protocol summary

Study aim

Evaluation the effectiveness of a mixture syrup, based on pomegranate and spearmint (vomigramint), on chemotherapy induced nausea and vomiting in breast cancer

Design

In this Double- blind, Parallel, randomized clinical trial , 60 eligible patients with breast cancer, referring to chemotherapy ward of Imam khomeini hospital, Sari, or Arian clinic, Amol, Iran, whom suffered from chemotherapy induced nausea and vomiting (CINV), (resistant to routine treatments), were selected purposefully. Participants were randomly divided into two arm parallel intervention and control group. Random allocation is done in the absence of research team, by statics expert of Mazandaran university of medical sciences, using a computerized random allocation software table tool. Hereafter, similar drug packages with different 4- digit codes were determined for patients by statics expert, using random allocation software. These codes are putted in envelopes, which then opened randomly, by research fellow, and drug or placebo with the same code is delivered to patients.

Settings and conduct

This study is about women with primary, non-metastatic breast cancer, whom suffered from resistant CINV, and will be done in chemotherapy ward of Imam khomeini hospital, Sari, and Arian clinic, Amol, in 5 months estimated period of time. This study is a double-blind, randomized, parallel clinical trial study in which patients and research fellow are blinded, by providing placebo, as similar as possible to drug, in smell, color, density, volume and containing bottle.

Participants/Inclusion and exclusion criteria

Inclusion criteria s: Documentary primary breast cancer diagnosis, At least 1 course of similar chemotherapy regimen is done, More than 18 years old, Experience of

any degree of post chemotherapy nausea and vomiting, without dramatic response despite using routine anti-emetic drugs, At least two courses of chemotherapy is proceeding, Also Patient's Satisfaction is prominently considered, Exclusion criteria s: Radiotherapy accompanying with chemotherapy simultaneously; Using anti-coagulant drugs in therapeutic dosage or having coagulation disorders; Using unusual or non permitted drugs or methods for treatment of nausea and vomiting other than intervention; Eating or hypersensitivity to pomegranate or spearmint in past week ; Having secondary or metastatic cancers; Nausea and vomiting by other secondary organic causes.

Intervention groups

In intervention group, pomegranate and spearmint syrup (Vomigramint) is taken, three times a day, each time ten cc, with a glass of cool water, half an hour before each meal In control group, mixture of distilled water and eatable caramel syrup is taken, three times a day, each time ten cc, with a glass of cool water, half an hour before each meal

Main outcome variables

Severity of nausea; Frequency of vomiting in three different phases

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171118037516N1**

Registration date: **2018-03-06, 1396/12/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-06, 1396/12/15**

Update count: **0**

Registration date

2018-03-06, 1396/12/15

Registrant information

Name

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Name of organization / entity

The Medical school of Mazandran university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-19, 1396/11/30

Expected recruitment end date

2018-07-22, 1397/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of a mixture-syrup based on pomegranate and spearmint (Vomigramint), compared with placebo, on Chemotherapy induced nausea and vomiting (CINV) in breast cancer

Public title

Evaluation the effectiveness of pomegranate and spearmint (Vomigramint) syrup on CINV

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

More than 18 years-old aging Documentory report for Breast cancer At least one session of chemotherapy is done prior to intervention Taking similar and one-day chemotherapy regimen At least two sessions of chemotherapy is proceeding History of any level of CINV (qualitative or quantative), despite taking routine anti-emetic drugs.

Exclusion criteria:

Total or upper abdomen radiotherapy, accompanying with chemotherapy simultaneously Consumption therapeutic dosage of anti-coagulant agents History of coagulopathic disorders Taking anti- emetic drugs or methods, except those permitted drugs in this study History of hypersensitivity to pomegranate or spearmint Pomegranate or spearmint consumption during one week prior to intervention Suffering from other cancers or metastatic breast cancer simultaneously Having other problems or diseases causing nausea(e.g. Hypertension, Liver or Renal failure, Diabetes mellitous , Constipation)

Age

From 18 years old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups by using Block randomization method. Personalized randomization method is done by using random allocation software. Samples divided in ten blocks and six rows. Selection of random digits for blocks is done by random allocation software table tool. Drug and placebo are prepared for patients with similar specificity and different 4 digit numbers, assigned by statics expert e. Researcher and patients do not know about drug or placebo

Blinding (investigator's opinion)

Double blinded

Blinding description

Random allocation and blinding was done this way: In the absence of research team, The statics expert of Mazandaran university of medical sciences, by using a computerized random allocation software table tool, blindly allocated patients into intervention or control groups. Hereafter, drug package with 4- digit codes were determined for patients by research fellow. Thus, this study is a randomized and double-blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Mazandaran University of Medical Sciences

Street address

Research and technology center of mazandaran university of medical sciences, Moallem square, Moallem avenue, Sari, Mazandaran, Iran

City

Sari

Province

Mazandaran

Postal code

48175-861

Approval date

2018-01-13, 1396/10/23

Ethics committee reference number

IR.MAZUMS.REC.1396.10465

Health conditions studied

1

Description of health condition studied

nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

2

Description of health condition studied

Breast cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast of unspecified site, female

Primary outcomes

1

Description

Severity of nausea

Timepoint

Three days before intervention, One day after intervention, five days after intervention

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 patients with breast cancer, using syrup (250 cc bottle) contains of pomegranate juice and spearmint extract (with proportion of 2/1), produced with Persian medicine formulation, drinking three times per day and each time 10cc of syrup, pre-prandial, for 8 days (3 days before to 5 days after chemotherapy course, except the day of chemotherapy infusion).

Category

Treatment - Drugs

2

Description

Control group: 30 patients with breast cancer, using syrup (250 cc bottle) contains of distilled water and eatable caramel, with similar specifications to drug (as color, taste, density and volume), drinking three times

per day and each time 10cc of syrup, pre-prandial. for 8 days (3 days before to 5 days after chemotherapy course, except the day of chemotherapy infusion).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Seyede Sedighe Yousefi

Street address

Imam khomeini hospital, Razi street, Amirmazandarani avenue, Sari city, Mazandran province, Iran

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2

Recruitment center

Name of recruitment center

Amol Arian clinic

Full name of responsible person

Seyede sedighe yousefi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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

Sari 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 scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Seyede Sedighe Yousefi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available