

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Iranian traditional medicine remedy compared with placebo on resistant chemotherapy induced nausea and vomiting in breast cancer

Protocol summary

Summary

The main objective of this research is the role of the Persumac(Iranian traditional medicine remedy) on refractory chemotherapy induced nausea and vomiting in breast cancer patients. We assess effect of Persumac on the number and severity of nausea and vomiting in acute and delayed phase. Executive steps of study were: 1- Among patients referred for breast cancer, to the oncology clinic in Imam Reza hospital in Mashhad University of Medical Sciences; patients included in study who had at least one chemotherapy session and remain at least three sessions of Their chemotherapy sessions and had inclusion criteria. 2- The initial assessment of patients (Run- in): Concurrent with the visit of patient for chemotherapy (the first session of her/his chemotherapy in this study); also during interview, questionnaire was delivered. It took a full explanation of how to complete it and return the next session. 3- In the second session of chemotherapy (in this study); after eligibility qualification and obtaining consent form, patients randomly allocated into I-intervention(with Persumac- Bunium Persicum and Rhus Coriaria) and II- control(Lactose as Placebo) groups. The patients and researcher were blinded, In accordance with the study protocol, interventions take place. Questionnaire was delivered to the patient again. 4- (Wash out): Sixth day after the second session of chemotherapy until a day before the third session of chemotherapy determined as Wash out period. 5- In the third session of chemotherapy-in this study, after obtaining the previous questionnaire, patient received cross over interventions. Questionnaire delivered to the patient again. The interval between each session of chemotherapy was two weeks. Finally data analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061822806N1**

Registration date: **2016-05-22, 1395/03/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-22, 1395/03/02

Registrant information

Name

Sadegh Shokri

Name of organization / entity

Birjand university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3239 5833

Email address

shokris1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences and Researcher

Expected recruitment start date

2015-10-03, 1394/07/11

Expected recruitment end date

2016-05-20, 1395/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Iranian traditional medicine remedy compared with placebo on resistant chemotherapy induced nausea and vomiting in breast cancer

Public title

Effect of Iranian traditional medicine remedy on chemotherapy induced nausea and vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Female, Definitive diagnosis of breast cancer by oncologists and a pathology report by pathologist, Age>18 years, History of chemotherapy induced nausea and vomiting resistant to conventional therapy, Normal tests for CBC, urea, creatinine, Alt, Ast, Bilirubin, FBS, Na, K, Have at least three sessions of chemotherapy ahead. Exclusion criteria: Total or upper abdominal radiation therapy along with chemotherapy-Taking anticoagulants, Use of other drugs/therapy for nausea and vomiting that not prescribed in this study, Hypersensitivity to Sumac or Bunium Persicum, Use of sumac and Bunium Persicum in seven days prior to the intervention, Diseases of the digestive system, Diseases that may associate with nausea and vomiting (such as hypertension, liver failure and kidney, digestive problems), Milk allergy, Losing of two consecutive or three intermittent doses of intervention.

Age

From **18 years** old to **70 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features

Random allocation and blinding was done this way: In the absence of research team, The laboratory expert, by using a computerized random number table, blindly allocated patients to intervention or control groups for second session chemotherapy in study. Hereafter, drug package codes were determined for patients. In cross over, the expert announced drug packages codes to researcher for delivery to the patients. Thus, this study is a randomized and double-blind.

Secondary Ids**1****Registry name**

Thai Clinical Trials Registry

Secondary trial Id

TCTR20160401004

Registration date

2016-04-01, 1395/01/13

Ethics committees**1****Ethics committee****Name of ethics committee**

Medical ethics committee of Mashhad University of Medical Sciences

Street address

University St., Ghoraischy Building

City

Mashhad

Postal code

91375-345

Approval date

2015-11-07, 1394/08/16

Ethics committee reference number

IR.MUMS.REC.1394.495

Health conditions studied**1****Description of health condition studied**

Nausea and vomiting

ICD-10 code

R-11

ICD-10 code description

Nausea and vomiting

2**Description of health condition studied**

Breast cancer

ICD-10 code

C50.9

ICD-10 code description

Breast, unspecified

3**Description of health condition studied**

Follow-up examination after chemotherapy for other conditions

ICD-10 code

Z09.9

ICD-10 code description

Follow-up examination after unspecified treatment for other conditions

Primary outcomes**1****Description**

Number of nausea in acute phase

Timepoint

Day 1 of intervention

Method of measurement

questionnaire

2**Description**

Number of vomiting in acute phase

Timepoint

Day 1 of intervention

Method of measurement

questionnaire

3**Description**

severity of nausea in acute phase

Timepoint

Day 1 of intervention

Method of measurement

Visual Analog Scale

4**Description**

severity of vomiting in acute phase

Timepoint

Day 1 of intervention

Method of measurement

Visual Analog Scale

Secondary outcomes**1****Description**

Frequency of nausea in delayed phase

Timepoint

day 2-5 of intervention

Method of measurement

questionnaire

2**Description**

Frequency of vomiting in delayed phase

Timepoint

day 2-5 of intervention

Method of measurement

questionnaire

3**Description**

severity of nausea in delayed phase

Timepoint

day 2-5 of intervention

Method of measurement

Visual Analog Scale

4**Description**

severity of vomiting in delayed phase

Timepoint

day 2-5 of intervention

Method of measurement

Visual Analog Scale

Intervention groups**1****Description**

2.7 gram Persumac, plus one drop of black zirah essential oil made in Adonis Goldaroo, three times daily half hour before meal with one glass cold water.

Category

Treatment - Drugs

2**Description**

2.7 gram lactose, three times daily half hour before meal with one glass cold water

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Oncology clinic, Imam Reza Hospital, Mashhad, Iran

Full name of responsible person

Taghizadeh Kermani, Ali

Street address

Department of Oncology, Imam Reza Hospital,
Mashhad University of Medical Sciences

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Mashhad University of
Medical Sciences

Full name of responsible person

Tafaghodi, Mohsen

Street address

Ghoraishy Building, University St, Mashhad, Iran

City

Mashhad

Grant name

930735

Grant code / Reference number

930735

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

Yes

Title of funding source

Vice chancellor for research, Mashhad 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
school of Persian and Complementary medicine
Full name of responsible person
Shokri, Sadegh
Position
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Other areas of specialty/work
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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