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 Persmac- 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., Ghoraishy 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 time daily half hour before meal with one glass cold water.
Category
Treatment - Drugs

2

Description
2.7 gram lactose, three time 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
Ph.D candidate of Persian medicine

Other areas of specialty/work

Street address
Bisim intersection, 6th jahad, opposite of Mehran gymnasium, Mashhad-Iran,

City
Mashhad

Postal code

Phone
+98 51 3855 2189

Fax
+98 51 3855 2188

Email
shokris1@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
School of Persian and Complementary medicine

Full name of responsible person
Nazari, Mohammad

Position
Ph.D

Other areas of specialty/work

Street address
Bisim intersection, 6th jahad, opposite of Mehran gymnasium, Mashhad-Iran,

City
Mashhad

Postal code
91388-13944

Phone
+98 51 3855 2189

Fax
+98 51 3853 5980

Email
NazariM@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
School of Persian and Complementary medicine

Full name of responsible person
Shokri, Sadegh

Position
Ph.D candidate of Persian medicine

Other areas of specialty/work

Street address
Bisim intersection, 6th jahad, opposite of Mehran gymnasium, Mashhad,Iran,

City
Mashhad

Postal code

Phone
+98 51 3855 2188

Fax
+98 51 3853 5980

Email
shokris1@mums.ac.ir

Web page address

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