Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of the protective effect of chamomile oral solution on the incidence of neurotoxicity caused by chemotherapy regimens containing paclitaxel in cancer patients

Protocol summary

Study aim

Effectiveness of chamomile oral solution in preventing neurotoxicity caused by regimens containing paclitaxel in cancer patients

Design

In this study, there is a three-way blind randomized clinical trial with placebo with parallel groups on 40 cancer patients.

Settings and conduct

Forty cancer patients in the Omid Hospital, Mashhad who meet the inclusion criteria will be included randomly to the intervention and placebo groups in equal proportions. In the drug group, starting one day before the paclitaxel injection, 5 cc of an oral solution containing chamomile hydroalcoholic extract (each 5 cc contains 500 mg of dry extract) prepared by Kimiagar Tous Pharmaceutical Company three times a day. to be The dosage of paclitaxel will be 175 mg/m2 every two or three weeks for 4 courses for a maximum of 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Suffering from cancer and starting chemotherapy regimen containing paclitaxel at a dose of 175 mg/m2; Age 18-70 years. Exclusion criteria: Liver failure (due to the change in drug clearance): If the ALT and AST tests are more than two to three times the normal level at the beginning of the treatment; Renal failure (GFR<30 ml/min); Taking supplements containing antioxidant compounds.

Intervention groups

In the drug group, starting one day before the paclitaxel injection, 5 cc of an oral solution containing chamomile hydroalcoholic extract (each 5 cc contains 500 mg of dry extract) prepared by Kimiagar Tous Pharmaceutical Company three times a day. In the placebo group, starting one day before the paclitaxel injection, 5 cc of placebo solution prepared by KimiagarTous Company three times a day. The dosage of paclitaxel will be 175 mg/m2 every two or three weeks for 4 courses for a maximum of 12 weeks in both groups.

Main outcome variables

Evaluation of neuropathy occurrence, based on NCI-CTC criteria version 3,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046990N14**
Registration date: **2023-10-06, 1402/07/14**
Registration timing: **prospective**

Last update: **2023-10-06, 1402/07/14**
Update count: **0**

Registration date

2023-10-06, 1402/07/14

Registrant information

Name

Sepideh Elyasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1588

Email address

elyasis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-11-21, 1403/09/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the protective effect of chamomile oral solution on the incidence of neurotoxicity caused by chemotherapy regimens containing paclitaxel in cancer patients

Public title
Investigating the effect of chamomile oral solution on neurological complications caused by chemotherapy regimens containing paclitaxel in cancer patients.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from cancer and starting chemotherapy regimen containing paclitaxel at a dose of 175 mg/m2.
age between 18-70 yers
Exclusion criteria:
Liver failure (due to the change in drug clearance): If the ALT and AST tests are more than two to three times the normal level at the beginning of the treatment, the patient will be excluded from the study. Renal failure (GFR<30 ml/min) Neuropathy at baseline Having diabetes or other disorders that cause neuropathy Taking supplements containing antioxidant compounds Use of neuromodulator drugs such as compounds containing calcium or magnesium and anticonvulsant drugs such as gabapentin and antidepressants from tricyclic antidepressants and serotonin-norepinephrine reuptake inhibitors. Taking warfarin alcohol consumption Smoking Lack of patient satisfaction Having a history of allergy to chamomile BMI>30 Use of other neurotoxic drugs in the chemotherapy regimen, such as platinums or vincristine Suffering from concurrent neuromuscular diseases such as myasthenia gravis Guillain Barre syndrome, multifocal motor neuropathy and chronic inflammatory demyelinating polyneuropathy
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done based on the table of random numbers prepared from randomization.com. In this study, the allocation of people to two groups will be done using the 4 permutation block method. In this method, A represents the person who receives the intervention and B represents the person who is placed in the control group. The letter A or B will be assigned to the drug or placebo by a person not involved in entering the patients, evaluating the patients, and analyzing the data, and will not be decoded until the end of the analysis. Considering the quadruple block; We give code 0 to AABB permutation, code 1 to ABAB permutation, code 2 to ABBA, code 3 to BAAB, code 4 to BBAA and code 5 to BABA.Then, using the table of random numbers, we randomly select a starting point and then consider 5 numbers in a row or column. Considering the order of the numbers in the table, we place the permutation corresponding to each number we come across, for example, if the first three numbers of the table of random numbers are 1, 0, and 5 respectively, the order of receiving treatment by the first 12 people in two groups, respectively From left to right it will be ABABAABBBABA. In this process of generating random numbers, we skip the numbers 6 to 9 to select blocks of four. Randomization type: 1- Simple 2- Blocked block 3- Stratified
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the drug packages prepared in the two intervention and control groups are the same, and the form of the oral formulation of the drug and the placebo are also similar to each other, and both are prepared by the same pharmaceutical company with a similar appearance and are provided to the plan administrators.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Qureshi Building, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
1394491388
Approval date
2023-08-28, 1402/06/06

Ethics committee reference number
IR.MUMS.REC.1402.145

Health conditions studied

1

Description of health condition studied
Various cancers treated by paclitaxel
ICD-10 code
C00-C97
ICD-10 code description
malignant neoplasms

Primary outcomes

1

Description
neuropathy
Timepoint
at baseline-after each course-at the end of study
Method of measurement
based on NCI-CTC (national cancer institute-common toxicity criteria version 5)

Secondary outcomes

1

Description
Sleep assessment
Timepoint
at the beginning of study-at the end of study
Method of measurement
Based on the Pittsburgh Sleep Quality Index

2

Description
Assessment of anxiety
Timepoint
at the beginning of study-at the end of study
Method of measurement
Generalized Anxiety Disorder scale questionnaire index

Intervention groups

1

Description
Intervention group: In the drug group, starting one day before the paclitaxel injection, three times a day each time in the amount of 5 cc of the oral solution containing the hydroalcoholic extract of chamomile (each 5 cc contains 500 mg of dry extract) every two or three weeks for 4 courses for It will be a maximum of 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: In the placebo group, a placebo is consumed three times a day, 5 cc each time. The dosage of paclitaxel will be 175 mg/m2 every two or three weeks for 4 courses for a maximum of 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid hospital
Full name of responsible person
Sepideh Elyasi
Street address
Koh Sangi St. - El Nandasht Intersection - Omid Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
9176613775
Phone
+98 51 3842 6082
Email
omidhos@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Mouhebati
Street address
Faculty of Medicine, Ferdowsi University, Vakilabad Boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
mouhebatim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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 general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sepideh Elyasi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy; Ferdowsi University; Vakilabad Boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
17871 91886
Phone
+98 51 3180 1588
Email
elyasis@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sepideh Elyasi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy; Ferdowsi University; VakilAbad Boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
17871 91886
Phone
+98 51 3180 1588
Email
elyasis@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sepideh Elyasi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy; Ferdowsi University; Vakilabad Boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
17871 91886
Phone
+98 51 3180 1588
Email
elyasis@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
No - There is not a plan to make this available
Title and more details about the data/document
The findings will be published in an article. Study protocol and statistical analysis will be used for article publication.
When the data will become available and for how long
One year after the end of the study it will be published and available in databases.
To whom data/document is available
If the funding sponsor allowed, the findings will be available for researchers, clinicians, and scientific

centers.

Under which criteria data/document could be used

The other researchers can use our findings in their review articles and meta analysis.

From where data/document is obtainable

For this purpose, you can contact with Sepideh Elyasi, at Clinical Pharmacy Department, School of Pharmacy, Vakil Abad Aven., Mashhad, Iran. Email: elyasis@mums.ac.ir

What processes are involved for a request to access data/document

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks

Comments