

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 platinum 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

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9176613775

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omidhos@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Mouhebat

Street address

Faculty of Medicine, Ferdowsi University, Vakilabad Boulevard

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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

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 addressFaculty of Pharmacy; Ferdowsi University; Vakilabad
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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

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate Professor

Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study ProtocolUndecided - 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 CodeUndecided - 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/documentThe 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