Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of curcumin supplementation on pain caused by neuropathy in patients treated with taxanes

Protocol summary

Study aim
Since taxane drugs have many side effects for chemotherapy and their most important complication is neuropathic pain and cannot be controlled and treated with its prescribed drug, gabapentin, this project is very important and it is hoped that curcumin supplementation will have a significant effect on control and treatment. Have neuropathic pains caused by taking taxanes.

Design
Drugs will be coded by a third party (outside the study). Then the drug label will be removed and the numbered drugs will be provided to the student. The student only sees the number and does not know the type of medicine. The patient only knows that he is participating in a study that will help his treatment process and is completely unaware of the prescription of the type of medicine to be taken. After prescribing the drugs and recording the data by the student, the information is provided to the statistical analyst. After the statistical analysis, the data will be provided to the researcher responsible for writing the article. In order to write the article, the main researcher will match the number of drugs with the type by referring to the third person.

Settings and conduct
Kerman Javadalameh Clinic

Participants/Inclusion and exclusion criteria
Inclusion: All cancer patients who show symptoms of neuropathy caused by taxane chemotherapy drugs and are confirmed by NCV test. Non-entry: Cancer patients who have neuropathy caused by factors other than chemotherapy drugs, such as diabetics, pregnant and lactating mothers, people who receive painkillers, such as morphine

Intervention groups
1- Treatment group receiving curcumin capsules 2- Control group receiving placebo 3- Positive control group receiving gabapentin

Main outcome variables
Severity of neuropathy (based on questionnaire items) of patients receiving taxane drugs

General information

Reason for update

Acronym
کورکومین و نوروپاتی داروی شیمی درمانی

IRCT registration information
IRCT registration number: **IRCT20220802055602N1**
Registration date: **2022-08-20, 1401/05/29**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-20, 1401/05/29**
Update count: **0**

Registration date
2022-08-20, 1401/05/29

Registrant information
Name
naeem nikpour
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 34 3132 8000
Email address
fatemeh.dsdt4@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-11, 1401/05/20

Expected recruitment end date
2022-10-12, 1401/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of curcumin supplementation on pain caused by neuropathy in patients treated with taxanes

Public title
The effect of curcumin supplementation on pain caused by neuropathy in patients treated with taxanes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Having symptoms of neuropathy Confirmation of neuropathy by ncv test and doctor's examination
Exclusion criteria:
Cancer patients who have neuropathy caused by factors other than chemotherapy drugs, such as diabetics, pregnant and lactating mothers, people who receive painkillers such as morphine

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple, individual randomization is random allocation to intervention and control groups through a table of random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
Drugs will be coded by a third party (external to the study) (eg, main treatment group #1, placebo #2, and positive control #3). Then the drug label will be removed and the numbered drugs will be given to the student (responsible for following up and correct prescription of drugs). The student only sees the number and does not know the type of medicine. The patient only knows that he is participating in a study that will help his treatment process and is completely unaware of the prescription of the type of medicine to be taken. After prescribing the drugs and recording the data by the student, the information is provided to the statistical analyst (who also only knows the number and does not know the type of drug). After the statistical analysis, the data will be provided to the researcher responsible for writing the article. In order to write the article, the main researcher will match the number of drugs with their type by referring to a third party (outside the study).

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Kerman University of Medical Sciences

Street address
haft bagh alavi

City
kerman

Province
Kerman

Postal code
7616913555

Approval date
2022-06-05, 1401/03/15

Ethics committee reference number
IR.KMU.REC.1401.150

Health conditions studied

1

Description of health condition studied
Neuropathy caused by receiving taxanes

ICD-10 code

ICD-10 code description

2

Description of health condition studied
cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
شدت نوروپاتی (بر اساس آیتم های پرسشنامه) بیمارانی که داروی شیمی درمانی دسته تاکسان ها دریافت میکنند

Timepoint
Evaluation of neuropathy in patients is before the administration of drugs, in the middle of the administration period (45 days after the administration of the interventions i.e. the administration of the first dose of drugs, placebo and positive control) and after the treatment (up to 1 month after the last administration of the interventions).

Method of measurement
Nerve conduction speed test, doctor's examination and

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients with chemotherapy-induced neuropathy who receive 500 mg curcumin tablets once a day for up to 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kerman Javadalameh Clinic
Full name of responsible person
naeem nikpour
Street address
abozar 25
City
kerman
Province
Kerman
Postal code
7617763811
Phone
+98 34 3251 2098
Email
kmuamar@kmu.ac.i

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Reza malekpour afshar
Street address
ebne sina
City
kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3226 3719
Email
kmuamar@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Rezaie
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person

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fatemeh.dsdt4@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Failure to make a decision

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not 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

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments