

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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 نورویاتی 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 نورویاتی (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

Street address

HAFT BAGH ALAVI

City

kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5690

Email

Fatemeh.dsdt4@gmail.com

Person responsible for scientific 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

Street address

haft baghe alavi

City

kerman

Province

Kerman
Postal code
7616913555
Phone
+98 34 3132 5690
Email
Fatemeh.dsdt4@gmail.com

Person responsible for updating data

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
Street address
haft bagh alavi
City
kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5690
Email
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