

# 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

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#### Province

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7616913555

#### Phone

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#### 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

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student

#### Latest degree

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Rezaie  
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student  
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7616913555  
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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