Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The effect of curcumin on the prevention of paclitaxel and platinum compounds-induced neuropathy in cancer patients: a randomized double-blinded controlled clinical trial

Protocol summary

Study aim

The effect of curcumin on the prevention of neuropathy in cancer patients undergoing chemotherapy with paclitaxel and platinum compounds

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients. Excel software RND() function is used for randomization. Patients are evaluated for neuropathy on days 1, 4, 7, 14, and 28.

Settings and conduct

The study is performed on cancer patients referred to Shahid Sadoughi Hospital, Yazd, Iran, under the supervision of an oncologist. Drugs and placebo are prepared uniformly and patients receive one of the drugs or placebo based on random numbers. Neither the doctor nor the patient knows the contents of the container containing the medicine.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20-50 years Initiation of paclitaxel and platinum compounds in cancer patients Inclusion criteria: History of allergy to curcumin or turmeric Drug addiction Existence of diseases such as diabetes, alcoholism that cause neuropathy Taking drugs such as amiodarone, colchicine, isoniazid, ethambutol that cause neuropathy Taking drugs such as tricyclic antidepressants (TCA) , selective serotonin reuptake inhibitors (SSRI), especially venlafaxine, duloxetine, pregabalin, gabapentin that mask the symptoms of neuropathy.

Intervention groups

Intervention group: Daily consumption of 80 mg of oral curcumin along with standard treatment of the patient Control group: daily consumption of one placebo oral capsule along with the standard treatment of the patient

Main outcome variables

Neuropathy score based on the standard neuropathic pain questionnaire

General information

Reason for update

A slight change in the title changes to platinum compounds instead of carboplatin Change the number of participants from 30 to 35 in each group Change the inclusion age from 18 to 20 Minor change in patient follow-up times

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045356N6**
Registration date: **2021-07-29, 1400/05/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-03, 1401/04/12**
Update count: **1**

Registration date

2021-07-29, 1400/05/07

Registrant information

Name

Mohsen Zabihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3865

Email address

mzabihi100@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-10-07, 1400/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of curcumin on the prevention of paclitaxel and platinum compounds-induced neuropathy in cancer patients: a randomized double-blinded controlled clinical trial

Public title

The effect of curcumin on the prevention of paclitaxel and platinum compounds-induced neuropathy in cancer patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20-50 years Initiation of the treatment with paclitaxel and platinum compounds in cancer patients

Exclusion criteria:

History of allergy to curcumin or turmeric Having diseases that cause neuropathy such as diabetes or conditions such as alcoholism.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

Curcumin and placebo are uniformly divided into two groups of drug containers that are labeled A or B in terms of the shape of the drug and the container containing the drug. In such a way that the doctor and the patient do not know the type of medicine in each medicine container. Patients who meet the inclusion criteria receive one of the drugs labeled A or B based on the RND() function of Excel software and take one number daily for 42 days, and they are evaluated during and after the intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

The medicine and placebo are placed in uniform containers and the doctor and the patient do not know the type of medicine prescribed in each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of ʾShahid Sadoughi University of Medical Sciences

Street address

Alem sq.

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2021-06-30, 1400/04/09

Ethics committee reference number

IR.SSU.MEDICINE.REC.1400.134

Health conditions studied

1

Description of health condition studied

Chemotherapy induced neuropathy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The neuropathy score is determined based on the Michigan Neuropathy Screening Instrument (MNSI) questionnaire, which includes a test with 20 yes / no questions.

Timepoint

Days 1, 4, 7, 14, 28 science starting internention

Method of measurement

Patient examination and Michigan Neuropathy Screening Instrument (MNSI) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Daily recipient of 80 mg of oral

curcumin from Sina Droo Pharmaceutical Company with Sina Curcumin brand for 28 days. Patients are evaluated for neuropathy on days 1, 4, 7, 14and 28

Category

Prevention

2

Description

Control group: Daily recipient of one oral capsule containing starch as placebo from Pharmacy school for 28days. Patients are evaluated for neuropathy on days 1, 4, 7, 14and 28

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Dr. Mohsen Zabihi

Street address

Alem sq.

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۱۷۳۱۴۹

Phone

+98 35 3820 3419

Email

mzabihi100@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mohsen Mirzaie

Street address

Bahonar sq.

City

Yazd

Province

Yazd

Postal code

۸۹۱۶۹۷۸۴۷۷

Phone

+98 35 3726 3733

Email

dvc.research@ssu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mohsen Zabihi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Alem sq.

City

Yazd

Province

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۸۹۱۵۱۷۳۱۴۹

Phone

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Email

mzabihi100@gmail.com

Person responsible for scientific inquiries

Contact

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Yazd University of Medical Sciences

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Dr. Mohsen Zabihi

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Email
mzabihi100@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Mohsen Zabihi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
۸۹۱۵۱۷۳۱۴۹
Phone
+98 35 3820 3419
Email
mzabihi100@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available