

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The Evaluation of the Preventive Effect of Metformin on Paclitaxel-Induced Peripheral Neuropathy

Protocol summary

Study aim

Evaluation of the preventive effect of metformin on paclitaxel-induced peripheral neuropathy

Design

Two arm parallel group & single blinded phase II randomized clinical trial

Settings and conduct

This study will be conducted on cancer patients referred to radiation oncology department of Namazi hospital in Shiraz in 2019. The case group (n=30) take 500 mg metformin Po Bid during chemotherapy with Paclitaxel (Paclitaxel; 175 mg/m² IV infusion during 3 hours every 2 weeks or 3 weeks), and control group (n=30) will not receive any additional medications during chemotherapy. Nerve conduction study (NCS) will be done at the beginning and the end of study for evaluating the change of neuropathy in cases versus controls. The patient will be unaware of medication content (single blinded). Adverse effects of intervention will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with histologically confirmed cancer, stage I - IV; Age = or > 18 years old and < 75 years old; Non-diabetics; Patients scheduled to undergo paclitaxel chemotherapy for cancer; Adequate hepatic and renal functions; ECOG performance status of 0 or 1; Signing the informed consent. Exclusion criteria: Patients with diabetes mellitus; A history of clinically significant hypersensitivity reaction to medications; Patients who are currently using metformin; Metformin induced neuropathy at 12 week

Intervention groups

The cancer patients in the case group will be taken the 500 mg metformin Po Bid during chemotherapy with Paclitaxel. The cancer patients in the control group will not be taken any additional medication during chemotherapy.

Main outcome variables

The primary outcome is the prevention of paclitaxel-

induced peripheral neuropathy, and the secondary outcome includes side effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190813044526N1**

Registration date: **2019-09-23, 1398/07/01**

Registration timing: **prospective**

Last update: **2019-09-23, 1398/07/01**

Update count: **0**

Registration date

2019-09-23, 1398/07/01

Registrant information

Name

Samaneh Sadeghian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4320

Email address

sadeghian_s@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-27, 1398/07/05

Expected recruitment end date

2019-12-26, 1398/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Evaluation of the Preventive Effect of Metformin on Paclitaxel-Induced Peripheral Neuropathy

Public title

The Effect of Metformin on Neuropathy

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Non-diabetic patients with histologically confirmed cancer; scheduled to undergo paclitaxel chemotherapy for cancer.

Exclusion criteria:

Patients with diabetes mellitus; A history of clinically significant hypersensitivity reaction to medications; Pregnancy; Patients who are currently using metformin; Metformin induced neuropathy at 12 week

Age

From **18 years** old to **75 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this trial, subjects will be randomly assigned to one of two intervention and control groups using the random number table. There are no prerequisites for assigning individuals to groups. The randomization unit is individual. Each participant will have an equal chance of being placed in each group. In this study, blinding is done by the project colleagues and the patient will not know the contents of the drug.randomization with individual randomization unit.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, a single blinding will be performed, the patient will not be aware of the drug content. So, the patient considers it to be part of the treatment process and to control the side effects of chemotherapy.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Faculty of medicine, Zand Avenue

City

Shiraz

Province

Fars

Postal code

71937-11351

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.SUMS.MED.REC.1398.318

Health conditions studied**1****Description of health condition studied**

Drug-induced Peripheral polyneuropathy

ICD-10 code

G62.0

ICD-10 code description

Drug-induced polyneuropathy

Primary outcomes**1****Description**

Prevention of paclitaxel-induced peripheral neuropathy

Timepoint

Before and after intervention (week 12)

Method of measurement

Nerve conduction study

Secondary outcomes**1****Description**

Side effects

Timepoint

Weekly during intervention course

Method of measurement

Taking a history from the patient

Intervention groups**1****Description**

Intervention group: Receiving 500 mg metformin Po Bid during chemotherapy with Paclitaxel

Category

Prevention

2**Description**

Control group: Without receiving additional medications during chemotherapy

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Namazi hospital

Full name of responsible person

Ahmad Mosallaei

Street address

Thirty-Sixth room, Department of radiation oncology, Namazi hospital, Namazi square

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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Deputy of Research, Shiraz University of Medical Sciences, Zand Avenue

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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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Samineh Sadeghian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Forty-second room, Department of radiation oncology, Namazi hospital, Namazi square

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Ahmad Mosallaei

Position

Full professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Web page address<http://www.sums.ac.ir>**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about main outcomes of the study

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Researchers in universities and scientific and research centers

Under which criteria data/document could be used

In order to improve the treatment of the disease and subsequent research and with the permission of the authors

From where data/document is obtainable

Department of radiation oncology of Shiraz university of medical sciences

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

Sending the request in writing or by email to the authors

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

Shiraz University of Medical Sciences

Full name of responsible person

Samineh Sadeghian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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