

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of pregabalin effect on treatment of Oxaliplatin-induced-neuropathy in patients with colorectal cancer with Folfox regime

Protocol summary

Study aim

Determining the effect of pregabalin drug in the treatment of neuropathy caused by oxaliplatin treatment in colorectal cancer patients with Folfox treatment regimen.

Design

This study will be conducted as a two-sided clinical trial in two intervention and control groups during the year 2023 in the hematology and oncology departments of Shahid Beheshti Hospital in Qom. A lottery method will be used to assign patients to two intervention and control groups. In order to observe blinding, the researcher and the examiner will be unaware of the type of treatment group of the patients. The mentioned patients will be divided into two equal groups. In the first group, patients will receive pregabalin chemotherapy at a dose of 75 mg every 12 hours for one month in the first month, in addition to the main cancer treatment regimen. But in the second group of patients, they will only receive treatment with the main cancer treatment regimen drugs.

Settings and conduct

This study will be conducted as a double-blind in the hematoncology departments of ShahidBeheshti Hospital. For blinding, researcher and examiner will be unaware.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of colorectal cancer, Age over 18 years, Not using another chemotherapy regimen at the same time. Exit criteria: Previous history of neuropathy, Diagnosis of polymyositis, Renal failure (GFR less than 50), Liver failure (liver enzymes more than 2-3 times normal), Diabetic patients.

Intervention groups

In the intervention group, in addition to the main cancer treatment regimen, patients will also receive pregabalin at a dose of 75 mg every 12 hours for one month in the first month.

Main outcome variables

The degree of neuropathy in these patients will be

measured based on a 0-10 grading scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231022059806N1**

Registration date: **2023-11-05, 1402/08/14**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-05, 1402/08/14**

Update count: **0**

Registration date

2023-11-05, 1402/08/14

Registrant information

Name

masoud aliakbarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3612 2000

Email address

amirqeqe@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-29, 1402/08/07

Expected recruitment end date

2024-10-28, 1403/08/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Evaluation of pregabalin effect on treatment of Oxaliplatin-induced-neuropathy in patients with colorectal cancer with Folfox regime
Public title	pregabalin effect on Oxaliplatin-induced-neuropathy
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Colorectal cancer diagnosis Age above 18 years Not using other chemotherapy regimen at the same time Exclusion criteria: Previous history of neuropathy Diagnosis of polymyositis Renal failure (GFR less than 50) Liver failure (liver enzymes more than 2-3 times normal) Diabetic patients.
Age	From 18 years old
Gender	Both
Phase	3
Groups that have been masked	• Outcome assessor • Data analyser
Sample size	Target sample size: 176
Randomization (investigator's opinion)	Randomized
Randomization description	A lottery method will be used to assign patients to two intervention and control groups. In the first stage, groups are written in the form of group A, B. Then, a lottery is drawn between the two groups to determine which is the intervention group and which is the control group.
Blinding (investigator's opinion)	Double blinded
Blinding description	In this study, the data analyst and the outcome assessor will be unaware of the type of group therapy of the patients. The data in the form of questionnaires A and B will be given to the person analyzing the final data so that they are unaware of the treatment group. The outcome evaluator is not involved in the way of dividing the patients and does not know which patients have received the intervention and will only complete the questionnaire and evaluate the outcome.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Research Ethics committee of Qom University Medical Sciences
Street address	Saheli St., Qom University of Medical Sciences, Qom.
City	qom
Province	Ghoum
Postal code	3713649373
Approval date	2023-03-13, 1401/12/22
Ethics committee reference number	IR.MUQ.REC.1402.003
Health conditions studied	
1	
Description of health condition studied	colorectal cancer
ICD-10 code	C19
ICD-10 code description	Malignant neoplasm of rectosigmoid junction
Primary outcomes	
1	
Description	The amount of neuropathy in these patients will be measured.
Timepoint	In order to check the duration of neuropathy in these patients, this questionnaire will be completed 3 months and 6 months after the end of treatment.
Method of measurement	The amount of neuropathy in these patients will be measured based on a grading scale of 0 to 10. In assessing the severity of painful neuropathy based on this criterion: 0 indicates that the patient has no pain and 10 indicates the most pain that the patient has ever experienced.
Secondary outcomes	empty
Intervention groups	
1	
Description	Intervention group: In addition to the main cancer treatment regimen, patients will also receive pregabalin

chemotherapy at a dose of 75 mg every 12 hours for one month in the first month.

Category

Treatment - Drugs

2

Description

Control group: Patients treated with the main cancer treatment regimen will only receive it.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Qom

Full name of responsible person

Dr Masoud Aliakbarzadeh

Street address

Shahid Beheshti Hospital, Shahid Beheshti St., Qom.

City

Qom

Province

Ghoum

Postal code

3719964797

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amirqeqe@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Rahim Aali

Street address

No 83, Safashahr street, Qom

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3716993456

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+98 25 3285 2720

Email

aali@hlth.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

Masoud Aliakbarzadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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

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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

All information will be shared after de-identification.

When the data will become available and for how long

6 months after the results are published.

To whom data/document is available

All researchers working in educational and scientific institutions.

Under which criteria data/document could be used

If the information of this study is useful in collecting more extensive data.

From where data/document is obtainable

Dr.Aliakbarzadeh amirqege@gmail.com

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

After receiving the email, the data will be shared.

Comments