

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Vitamin E on oxaliplatin-induced peripheral neuropathy prevention in coloractal cancer

Protocol summary

Summary

The aim of the this study is evaluating the effect of Vitamin E administration on prevention of oxaliplatin-induced peripheral neuropathy in patients with colorectal cancer . Inclusion criteria was 18 to 75 years of age ; diagnosed with colorectal cancer ; scheduled to receive oxaliplatin-based regimens (FOLFOX 4) ; had more than 6 month life expectancy . exclusion criteria was previous history of peripheral neuropathy ; symptomatic peripheral neuropathy at entry into the study ; received other chemotherapy regimens ; currently receiving anticoagulants ; platelet aggregation inhibitors ; opioids ; anticonvulsants ; tricyclic antidepressants ; previous history of hemorrhagic stroke . Seventy patients with colorectal cancer and scheduled to receive oxaliplatin-based regimens are enrolled in this study . The sample size was calculated on the assumption $\alpha = 0.05$ and power = 80%. Enrolled patients were randomized into two groups (35/group) . First group received vitamin E at a dose of 400 mg daily and second group observed , until after sixth course of the oxaliplatin regimen . For oxaliplatin-induced peripheral neuropathy assessment , we used the symptom experience diary questionnaire . This questionnaire were completed at baseline, prior to each chemotherapy treatment, and after sixth course of chemotherapy completion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030621350N1**

Registration date: **2015-04-01, 1394/01/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-01, 1394/01/12

Registrant information

Name

Zeinab Salehi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7781 7995

Email address

zeinab_salehi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Isfahan university of medical sciences

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2015-05-01, 1394/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Vitamin E on oxaliplatin-induced peripheral neuropathy prevention in coloractal cancer

Public title

Vitamin E in oxaliplatin-induced neuropathy prevention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : 18 to 75 years of age ; diagnosed with colorectal cancer ; scheduled to receive oxaliplatin-based

regimens (FOLFOX 4) ; had more than 6 month life expectancy exclusion criteria : previous history of peripheral neuropathy ; symptomatic peripheral neuropathy at entry into the study ; received other chemotherapy regimens ; currently receiving anticoagulants ; platelet aggregation inhibitors ; opioids ; anticonvulsants ; tricyclic antidepressants ; previous history of hemorrhagic stroke

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jirib , Darvaze Shiraz

City

Isfahan

Postal code

Approval date

2014-04-13, 1393/01/24

Ethics committee reference number

293032

Health conditions studied

1

Description of health condition studied

cancer of colorectal

ICD-10 code

C19

ICD-10 code description

Malignant neoplasm of rectosigmoid junction

2

Description of health condition studied

pripheral neuropathy

ICD-10 code

G62.0

ICD-10 code description

Drug-induced polyneuropathy

Primary outcomes

1

Description

peripheral neuropathy

Timepoint

before study and then 3 months later

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

in intervention group :vitamin E 400 mg daily

Category

Prevention

2

Description

Control group were observed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Seyedoshohada Hospital

Full name of responsible person

Zeinab Salehi

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan of University

Medical Sciences
Full name of responsible person
 Zeinab Salehi
Street address
 Hezar Girib , Darvaze Shiraz
City
 Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Vice Chancellor for research of Isfahan of University
 Medical Sciences
Proportion provided by this source
 100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
 Isfahan University of Medical Sciences
Full name of responsible person
 Zeinab Salehi
Position
 Resident
Other areas of specialty/work
Street address
 Hezarjerib Street
City
 Isfahan
Postal code
Phone
 +98 912 490 8319
Fax
Email
 zeinab_salehi@med.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
 Isfahan University of Medical Sciences

Full name of responsible person
 Mahnaz Roayaei
Position
 Assistant professor
Other areas of specialty/work
Street address
 Hezarjerib Street
City
 Isfahan
Postal code
Phone
 +98 31 3792 2445
Fax
Email
 Roayaei@med.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
 Isfahan University of Medical Sciences
Full name of responsible person
 Zeinab Salehi
Position
 Resident
Other areas of specialty/work
Street address
 Isfahan
City
 Isfahan
Postal code
Phone
 00
Fax
Email
 zeinab_salehi@med.mui.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty