

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Investigating the effectiveness of vitamin E in reducing the incidence of chronic neurotoxicity caused by oxaliplatin in patients with colon cancer undergoing adjuvant chemotherapy

Protocol summary

Study aim

Determining the effectiveness of vitamin E drug in reducing cases of chronic neurotoxicity caused by oxaliplatin drug

Design

Clinical trial with control group, with parallel groups, double-blind, randomized. The rand function of Excel software was used for randomization.

Settings and conduct

The study will be conducted in Hazrat Rasool Akram Hospital, Iran University of Medical Sciences. Colon cancer is diagnosed using a biopsy. Neuropathy caused by chemotherapy is defined as the frequency of occurrence of different severities of neurotoxicity throughout the treatment period, the severity of which will be determined based on NCI-CTCAE_ver3 criteria. The study is double-blind, and patients and researchers investigating neuropathy symptoms will be unaware of the grouping.

Participants/Inclusion and exclusion criteria

Entry requirements: Any patient with colon cancer referred to the hospital
Conditions of non-entry: None

Intervention groups

Intervention group: one hundred and eighty doses daily of vitamin E 400 mg. Control group: one hundred and eighty doses daily of placebo.

Main outcome variables

Reducing the occurrence of chronic neurotoxicity caused by chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180313039085N3**
Registration date: **2023-02-08, 1401/11/19**

Registration timing: **prospective**

Last update: **2023-02-08, 1401/11/19**

Update count: **0**

Registration date

2023-02-08, 1401/11/19

Registrant information

Name

Tayeb Ramim

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6683 0007

Email address

tramim@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of vitamin E in reducing the incidence of chronic neurotoxicity caused by oxaliplatin in patients with colon cancer undergoing adjuvant chemotherapy

Public title

Investigating the effectiveness of vitamin E drug in reducing the incidence of chronic neurotoxicity caused by oxaliplatin drug

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Colon cancer patients are candidates for adjuvant chemotherapy

Exclusion criteria:

Patients' unwillingness to participate in the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and outcome assessors will be blinded to study group allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine

Street address

School of Medicine, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-04-27, 1400/02/07

Ethics committee reference number

IR.IUMS.FMD.REC.1400.077

Health conditions studied

1

Description of health condition studied

Drug-induced neurotoxicity

ICD-10 code

62.0

ICD-10 code description

Drug-induced neurotoxicity

Primary outcomes

1

Description

Neurotoxicity

Timepoint

1, 2, 3, 4, 5 and 6 months after the start of the study

Method of measurement

NCI-CTCAE-ver3 criterion

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oral vitamin E soft gelatin capsule with a dose of 400 international units, one daily for 180 days, is manufactured by Porateb Gostar Iranian pharmaceutical factory.

Category

Prevention

2

Description

Control group: Soft gelatin capsule without any active ingredient, one daily for 180 days, manufactured by Porateb Gostar Iranian Pharmaceuticals.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasoole Akram Hospital

Full name of responsible person

Tayeb Ramim

Street address

Hazrate Rasoole Akram Hospital, Niayesh St, Satarkhan Av

City

Tehran

Province

Tehran
Postal code
1445613131
Phone
+98 21 6435 0000
Email
tayebramim@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hossein Kiwani
Street address
Hemmat Highway, next to Milad Tower
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Fax
Email
research-m@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Tayeb Ramim
Position
Deputy of Educational and Research
Latest degree
Medical doctor
Other areas of specialty/work
Epidemiology

Street address

Rasool Akram Hospital, Mazyar Mansori Ave, Satar Khan Ave.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6683 0007

Fax

Email

tayebramim@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Tayeb Ramim
Position
Deputy of Educational and Research
Latest degree
Medical doctor
Other areas of specialty/work
Epidemiology
Street address
Rasool Akram Hospital, Mazyar Mansori Ave, Satar Khan Ave.
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6683 0007
Fax
Email
tayebramim@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Tayeb Ramim
Position
Deputy of Educational and Research
Latest degree
Medical doctor
Other areas of specialty/work
Epidemiology
Street address
Rasool Akram Hospital, Mazyar Mansori Ave, Satar Khan Ave.
City
Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6683 0007

Fax**Email**

tayebramim@yahoo.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

Confidentiality of patient data

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable