

# 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