# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Evaluating the effect of Vitamin E and Vitamin A on Chemotherapy-Induced Oral Mucositis

## Protocol summary

**Study aim**
Determining the effect of vitamin E and A on chemotherapy-induced mucositis
**Design**
Non Randomized controlled clinical trial with parallel groups, phase 3 study on 28 samples
**Settings and conduct**
Based on the inclusion criteria, 28 samples of patients of Iran Mehr Birjand Hospital will be selected and will be divided into two groups of intervention and control. From the first day of study , the intervention group will receive vitamin E and vitamin A. All the patients will undergo oral examination on days 1, 7, 14, and 21 to evaluate the severity of the mucositis (according to World Health Organization scale).
**Participants/Inclusion and exclusion criteria**
Inclusion criteria: 1.Patients undergoing chemotherapy whose course of chemotherapy does not interaction with vitamins A and E. Exclusion criteria: 1.Using alcohol or cigarette
**Intervention groups**
Intervention group: Patients will receive vitamin E and vitamin A daily in 4 day period . Control group: will not receive any vitamin E and vitamin A
**Main outcome variables**
Oral mucositis

## General information

**Reason for update**
Record the number of samples Changes in study implementation details
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20210916052498N1**
Registration date: **2022-02-16, 1400/11/27**
Registration timing: **prospective**
Last update: **2023-12-03, 1402/09/12**
Update count: **1**
**Registration date**
2022-02-16, 1400/11/27

**Registrant information**
**Name**
Hossein Gholami
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2022-02-19, 1400/11/30
**Expected recruitment end date**
2022-09-23, 1401/07/01
**Actual recruitment start date**
2022-06-22, 1401/04/01
**Actual recruitment end date**
2022-10-22, 1401/07/30
**Trial completion date**
2022-10-22, 1401/07/30

**Scientific title**
Evaluating the effect of Vitamin E and Vitamin A on Chemotherapy-Induced Oral Mucositis

**Public title**
Evaluating the effect of Vitamin E and Vitamin A on Chemotherapy-Induced Oral Mucositis
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**

Chemotherapy’s indicated No interactions between vitamins E and A and chemotherapy

**Exclusion criteria:**

Chemotherapy’s Contraindicated Interactions between vitamins E and A and chemotherapy

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **28**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participant and Analyzer are blind. Participants were unaware of their group type and Blinding of the participants was done by receiving a placebo identical to the main drug. Analyzes was performed by blind people other than the main researchers.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Birjand University of Medical Sciences

**Street address**

Ghaffari

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Approval date**

2022-01-18, 1400/10/28

**Ethics committee reference number**

IR.BUMS.REC.1400.322

## Health conditions studied

### 1

**Description of health condition studied**

Oral Mucositis

**ICD-10 code**

K12.31

**ICD-10 code description**

Oral mucositis (ulcerative) due to antineoplastic therapy

## Primary outcomes

### 1

**Description**

Oral Mucositis

**Timepoint**

Days 1, 7, 14 and 21 after starting cancer treatment

**Method of measurement**

Clinical examination by a dentist based on World Health Organization oral mucositis grading scale.

## Secondary outcomes

### 1

**Description**

Pain severity

**Timepoint**

Days 1, 7, 14 and 21 after starting cancer treatment

**Method of measurement**

Visual Analogue Scale

## Intervention groups

### 1

**Description**

Intervention group: patients receive vitamin E (100 mg/day) and vitamin A (25000 Unit/day) for 4 days .

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Iranmehr Hospital

**Full name of responsible person**

Mohamad Amir Mohamadifard

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## Sponsors / Funding sources

**1**

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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**
Birjand 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**
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Birjand University of Medical Sciences
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Mohamad Amir Mohamadifard
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
No - There is not a plan to make this available

**Statistical Analysis Plan**
No - There is not a plan to make this available

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
No - There is not a plan to make this available

**Analytic Code**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available