Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 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
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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

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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

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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