Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Determining the effect of oxygen therapy during chemotherapy on 5FU-induced oral mucositis in colorectal cancer patients treated with FOLFOX regimen: A double-blind clinical trial

Protocol summary

Study aim
Determining the effect of oxygen therapy during chemotherapy on 5FU-induced oral mucositis in colorectal cancer patients treated with FOLFOX regimen

Design
A randomized, controlled, parallel-group, double-blind clinical trial with block randomization using blocks of two.

Settings and conduct
A randomized, double-blind trial at Kosar Hospital, Semnan, in colorectal cancer patients receiving FOLFOX. Patients will be randomized 1:1 to oxygen or room air during 5-FU bolus. The intervention group will receive oxygen via simple face mask for 30 minutes. Mucositis will be assessed by OMAS before treatment and after every two chemotherapy sessions. Participants and outcome assessor will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Non-metastatic colorectal cancer; FOLFOX including 5-FU; age 18–75 years; baseline SpO_2 >92% on room air; willingness and ability to complete treatment and follow-up. Exclusion Criteria: Oxygen intolerance; severe chronic pulmonary disease; active oral infection or significant oral/dental disease; concurrent head/neck radiotherapy; severe renal/hepatic insufficiency; active psychiatric or cognitive impairment; participation in another trial within 3 months; withdrawal or noncompliance with follow-up.

Intervention groups
Intervention Group: Patients will receive oxygen therapy via a simple face mask at 2 L/min for 30 minutes during each chemotherapy cycle (usually every two weeks), concurrently with the 5-FU bolus. Oral mucositis severity will be assessed before treatment and after every two chemotherapy sessions. Control Group: Patients will breathe room air normally without oxygen therapy or a mask during 5-FU bolus administration. Mucositis severity will be assessed at the same time points, and outcomes will be compared between groups until the end of follow-up.

Main outcome variables
Oral mucositis severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260908070968N1**
Registration date: **2026-10-01, 1405/07/09**
Registration timing: **prospective**

Last update: **2026-10-01, 1405/07/09**
Update count: **0**

Registration date
2026-10-01, 1405/07/09

Registrant information

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Homa Mozafariyan

Name of organization / entity

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-23, 1405/08/01

Expected recruitment end date
2027-01-21, 1405/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of oxygen therapy during chemotherapy on 5FU-induced oral mucositis in colorectal cancer patients treated with FOLFOX regimen: A double-blind clinical trial

Public title

Evaluating the effect of oxygen therapy during Chemotherapy on the prevention of Chemotherapy-Induced oral sores and Inflammation in patients with colorectal cancer

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a confirmed diagnosis of non-metastatic colorectal cancer, (based on medical records and confirmation by an oncologist) Receiving the FOLFOX chemotherapy regimen, including 5-fluorouracil (5-FU) administered as a bolus injection. Normal baseline blood oxygenation, defined as SpO_2 > 92% on room air. Ability to fully cooperate with the research team and attend treatment and follow-up sessions regularly.

Exclusion criteria:

History of hypersensitivity or intolerance to oxygen therapy. Presence of severe chronic pulmonary diseases, such as advanced chronic obstructive pulmonary disease (COPD) or uncontrolled asthma. Presence of active oral infection or chronic oral and dental diseases that could affect the assessment of oral mucositis severity. Concurrent receipt of radiotherapy to the head and neck region. Severe renal or hepatic insufficiency. Active psychiatric illness or cognitive impairment that may interfere with adequate understanding of the study procedures and informed consent. Participation in another clinical trial within the previous three months. Voluntary withdrawal from the study at any stage or failure to cooperate with the follow-up procedures.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated to the intervention or control group using block randomization with blocks of two, generated through the Sealed Envelope website. Randomization will be stratified by sex, and patients will be equally allocated to the two study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants and the data analyst will be blinded to group allocation. Participants will receive the intervention individually in separate rooms and will not have the opportunity to observe the intervention received by other participants. Information regarding group allocation and the type of intervention will not be disclosed to the participants. In the intervention group, oxygen therapy will be administered via a simple face mask for 30 minutes, while participants in the control group will remain under usual conditions and breathe room air. The intervention will be administered separately to each participant to minimize the possibility of revealing group allocation through observation of other participants. The personnel responsible for administering the intervention and the outcome assessor will not be blinded due to the nature of the intervention and the assessment process. For blinding of the data analyst, participant data will be coded using non-identifiable group codes (e.g., A and B) before statistical analysis. The code key will be kept by the principal investigator until completion of the statistical analysis. Therefore, the data analyst will not know which code represents the intervention or control group during the analysis. The group allocation codes will be revealed after completion of the statistical analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees of Semnan University Of Medical

Street address

Central Headquarters, Semnan University of Medical Sciences, Basij Blvd.

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Province

Semnan

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3514799442

Approval date

2026-06-22, 1405/04/01

Ethics committee reference number

IR.SEMUMS.REC.1405.075

Health conditions studied

1

Description of health condition studied
Colorectal cancer
ICD-10 code
C18
ICD-10 code description
Malignant neoplasm of colon

Primary outcomes

1

Description
Oral Mucositis Severity Score
Timepoint
Before the intervention and after every two chemotherapy sessions.
Method of measurement
Oral Mucositis Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive oxygen therapy via a simple face mask at 2 L/min for 30 minutes concurrently with the 5-FU bolus during each chemotherapy session. Oral mucositis severity will be assessed using the OMAS before the intervention and after every two chemotherapy sessions.
Category
N/A

2

Description
Control group: Patients will breathe room air normally without oxygen therapy or a mask during 5-FU bolus administration. Oral mucositis severity will be assessed using OMAS before treatment and after every two chemotherapy sessions.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Educational and Research Center
Full name of responsible person
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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
Semnan 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
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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable