Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Curcumin and Vitamin D Supplementation on Inflammatory Biomarkers and Nutritional Status in Patients with Colorectal Cancer: A Randomized Clinical Control Trial

Protocol summary

Study aim

Determining the effect of curcumin and vitamin D supplementation on inflammatory biomarkers and nutritional status of patients with colorectal cancer

Design

A randomized, double-blind, parallel-group, controlled clinical trial on 92 patients with colorectal cancer. Randomization was performed using random allocation software with a block size of 4 and a ratio of 1:1:1:1.

Settings and conduct

Patients with colorectal cancer referred to Amir Hospital, Mehr Clinic, Pardis Clinic, Hazrat Abolfazl Chemotherapy Center, and Motahari Clinic will be included in the study through convenience sampling method upon informed consent, according to the inclusion criteria and the absence of exclusion criteria. Blinding: The appearance, packaging, color, and size of the supplements and the dosage will be similar. At the beginning and end of the study, inflammatory factors, hand muscle strength, quality of life questionnaire, body composition analysis, and dietary components will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Colorectal cancer patients At least 3-month life expectancy Using chemotherapy method Nonallergic to turmeric Exclusion criteria: Unwillingness to participate in the study Not continuing chemotherapy

Intervention groups

Curcumin group: 80 mg of nanocurcumin daily and one placebo vitamin D tablet per week; Vitamin D group: one tablet of vitamin D (50,000) per week and two placebo nanocurcumin tablets per week; Curcumin and vitamin D group: 80 mg of nanocurcumin daily and one tablet of vitamin D (50,000) per week; Placebo group: Two tablets of curcumin daily and one placebo vitamin D tablet per week.

Main outcome variables

Interleukin 6, tumor necrosis factor alpha, C-reactive protein to albumin ratio, quality of life, body fat, lean body mass, body mass index, hand muscle strength, basal metabolism, dietary components

General information

Reason for update

Actual Start and End Dates of Patient Recruitment Actual start date: May 23, 2025 (1404/03/02) Actual end date: July 11, 2026 (1405/04/20)

Acronym

RCT

IRCT registration information

IRCT registration number: **IRCT20250110064340N1**
Registration date: **2025-03-27, 1404/01/07**
Registration timing: **prospective**

Last update: **2026-10-29, 1405/08/07**
Update count: **3**

Registration date

2025-03-27, 1404/01/07

Registrant information

Name

Marzieh Zamani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-21, 1404/02/31

Expected recruitment end date
2026-05-21, 1405/02/31
Actual recruitment start date
2025-05-23, 1404/03/02
Actual recruitment end date
2026-07-11, 1405/04/20
Trial completion date
empty

Scientific title
The Effect of Curcumin and Vitamin D Supplementation on Inflammatory Biomarkers and Nutritional Status in Patients with Colorectal Cancer: A Randomized Clinical Control Trial

Public title
The Effect of Curcumin and Vitamin D Supplementation on Inflammatory Biomarkers and Nutritional Status in Patients with Colorectal Cancer: A Randomized Clinical Control Trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with colorectal cancer 18-60 years of age At least 3 months of life expectancy Using chemotherapy BMI=18-30 kg/m2 Nonallergic to turmeric Not suffering from hypertension or renal, hepatic, or parathyroid disorders
Exclusion criteria:
Unwillingness to participate in the study Not continuing chemotherapy Fever greater than 38.5°C in three days before receiving the first dose of the supplementary drugs Known positive HIV serology Patients with other malignancies, Pregnancy and lactation
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **92**
More than 1 sample in each individual
Number of samples in each individual: **23**
Curcumin group: This group will receive 2 capsules of 40 mg of nanocurcumin daily (80 mg daily) and a placebo of vitamin D (500,000 IU) once a week, for 8 weeks. Vitamin D group: This group will receive one vitamin D tablet (500,000IU) weekly, and two placebo capsules (40 mg of nanocurcumin) daily (80 mg daily), for 8 weeks. Curcumin + Vitamin D group: This group will receive 2 capsules of 40 mg of Nano-curcumin (80 mg daily) and one tablet of vitamin D (500,000 IU) weekly, for 8 weeks. Curcumin + Vitamin D group: This group will receive 2 capsules of 40 mg of Nano-curcumin (80 mg daily) and one tablet of vitamin D (500,000 IU) weekly, for 8 weeks
Actual sample size reached: **89**

Randomization (investigator's opinion)
Randomized
Randomization description
Using random allocation software with a block size of 4 and a ratio of 1:1:1:1, the groups assigned to each participant will be labeled as A, B, C, D in identical sealed envelopes by an outsider.
Blinding (investigator's opinion)
Double blinded
Blinding description
The appearance, packaging, color, and size of the supplements and placebos will be similar. The supplements and placebos will be labeled by an outsider in line with the names of the groups with letters A, B, C, and D. Therefore, both the participants and the researcher will be unaware of the study groups and the use of the drug and placebo until the end of the study.
Placebo
Used
Assignment
Parallel
Other design features
The intervention will last for 8 weeks. The study participants will be divided into four groups:1- Curcumin group; 2- Vitamin D group; 3- Curcumin and vitamin D group; 4- Placebo group

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciencesal Science
Street address
Shiraz University of Medical Sciences, Zand Blvd
City
shiraz
Province
Fars
Postal code
7134814336
Approval date
2024-10-13, 1403/07/22
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1403.063

Health conditions studied

1

Description of health condition studied
colorectal cancer
ICD-10 code
C18.9
ICD-10 code description
Malignant neoplasm of colon

Primary outcomes

1

Description
Tumor necrosis factor alpha
Timepoint
At the beginning of the study (before the intervention) and 8 weeks after taking curcumin and vitamin D
Method of measurement
Using laboratory kit and ELISA method

2

Description
Interleukin 6
Timepoint
At the beginning of the study (before the intervention) and 8 weeks after taking curcumin and vitamin D
Method of measurement
Using laboratory kit and ELISA method

3

Description
C-reactive protein to albumin ratio
Timepoint
At the beginning of the study (before the intervention) and 8 weeks after taking curcumin and vitamin D
Method of measurement
Using a laboratory kit

4

Description
Hand muscle strength
Timepoint
At the beginning of the study (before the intervention) and 8 weeks after taking curcumin and vitamin D
Method of measurement
Using handgrip

5

Description
Quality of life
Timepoint
At the beginning of the study (before the intervention) and 8 weeks after taking curcumin and vitamin D
Method of measurement
Quality of life questionnaire

6

Description
Body mass index, basal metabolic rate, fat mass, fat-free mass, weight
Timepoint
At the beginning of the study (before the intervention) and 8 weeks after taking curcumin and vitamin D
Method of measurement
Using BIA

7

Description
Dietary components include energy, carbohydrates, protein, fat, and fiber
Timepoint
At the beginning of the study (before the intervention), 4 weeks after taking curcumin and vitamin D and 8 weeks after taking curcumin and vitamin D
Method of measurement
Using a 24-hour food recall questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Curcumin group: They will receive 2 capsules of 40 mg of nano-curcumin daily (80 mg daily) and one vitamin D placebo weekly for 8 weeks. Manufacturer: Exir Nano Sina Company-Tehran
Category
Treatment - Drugs

2

Description
Second intervention group: Vitamin D group: They will receive one vitamin D tablet (50000IU) per week and 2 nanocurcumin placebo capsules per day. Manufacturer: Zahravi Company-Tabriz
Category
Treatment - Drugs

3

Description
The third intervention group (Curcumin + Vitamin D group): Two capsules of 40 mg of nano-curcumin daily (80 mg daily) and one tablet of vitamin D (500,000 IU) weekly for 8 weeks
Category
Treatment - Drugs

4

Description
Control group: This group will receive two capsules of the nanocurcumin placebo daily and one capsule of the vitamin D placebo weekly for 8 weeks. The vitamin D placebo contains food grade paraffin, which is similar in shape and color to a vitamin D tablet. Manufacturer: Zahravi Company, Tabriz The curcumin placebo contains lecithin and food grade yellow dye E104, which is similar in shape and color to a curcumin tablet. Manufacturer: Exir Nano Sina Company, Tehran
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Oncology Hospital
Full name of responsible person
Reza Vojdani
Street address
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Web page address
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2

Recruitment center
Name of recruitment center
Mehr Oncology Clinic, Shahid Chamran Hospital
Full name of responsible person
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3

Recruitment center
Name of recruitment center
Pardis clinic
Full name of responsible person
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4

Recruitment center
Name of recruitment center
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Full name of responsible person
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5

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

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Full name of responsible person
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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Marzieh Zamani

Position
PHD student

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

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

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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