

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Evaluation of the effect of serum vitamin D levels on anxiety and depression in patients with colorectal adenocarcinoma

#### Protocol summary

##### Study aim

Investigation the effect of 25-hydroxy vitamin D3 (25OHD3) serum level on anxiety and depression in colorectal adenocarcinoma patients.

##### Design

A four arm parallel group non-randomised non-blinded before-after designed clinical trial without control group, 60 patients enrolled between march 2023 and march 2024.

##### Settings and conduct

In this trial, 60 cases of colorectal adenocarcinoma referring to Reza Radiotherapy Center will be included in the study based on the criteria. 50000 unit pearls of cholecalciferol from Zahrawi Pharmaceutical Company and 1000 units tabs from Omid Parsina Pharmaceutical Company will be given based on study's protocol: deficiency group: 50000 units weekly for 8 weeks, then 1000 units daily for 30 days, insufficiency: 1000 units daily. borderline: two days daily 1000 units, then one day off, sufficient: every three days, 1000 units. Serum 25OHD3 level by ELISA method and the anxiety and depression scores of the patients are measured by a questionnaire.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-65 years old; Ability to write and read in Persian; Ability to answer questionnaire questions. Exclusion criteria: Complicated diabetes or hypertension; History of visiting a psychiatrist or psychologist in the last 6 months or taking psychotropic drugs in the last 6 months; Pregnancy; Breastfeeding; Taking vitamin D or vitamin D3 analogs in the last 3 months; Vitamin D serum level more than 100 ng/ml; Serum level of ionized calcium more than 5.6 mg/dL.

##### Intervention groups

Deficiency group (D): 25OHD3 serum level below 12 ng/ml; Insufficiency group (I): 25OHD3 serum level 12-20 ng/ml; Borderline group (B): 25OHD3 serum level 20-30 ng/ml; Sufficient group (S): 25OHD3 serum level above 30 ng/ml

##### Main outcome variables

Zung S.D.S score; Zung S.A.S score; 25OHD3 serum level before intervention; 25OHD3 serum level after the end of intervention

##### General information

##### Reason for update

1. Modification of the Code of Ethics Committee due to the modification of the code announced on the Pajooheshyar website by the Ethics Committee of Islamic Azad University of Mashhad Medical Sciences Branch.
2. Minor protocol changes due to the use of Pearl 50000 units of Zahrawi Pharmaceutical Company along with 1000 unit tablets of Omid Parsina Damavand Pharmaceutical Company instead of Pearl 5000 units of Zahrawi Company due to the unavailability of Pearls of 5000 units in the pharmaceutical market.
3. Entering all new and non-new cases of patients with colorectal adenocarcinoma instead of entering new cases alone, due to the number of clients of Reza Radiotherapy and Oncology Sampling Center.
4. Addition of Omid Parsina Damavand pharmaceutical company to sponsors/credit suppliers due to the use of 1000 unit tablets of this company.
5. Removal of Mashhad University Jihad Laboratory from sponsors/credit providers due to the use of sampling center laboratory (Reza Radiotherapy and Oncology Center) in order to save money and time.
6. Measuring the serum level of 25OHD3 at the beginning and end of the intervention instead of measuring it monthly, due to the budget limitation and the unnecessary and lack of significant effect of the monthly measurement of 25OHD3 on the final result of the study.
7. Reducing the sample size from 60 people to 45 people due to budget restrictions and increased tariffs and non-cooperation of clients.
8. Addition of 22 Bahman Hospital in Mashhad to the sampling centers to provide the sample size for the study.
9. Removing "Ionized calcium serum level more than 5.6 mg/dL" from the exclusion criteria due to budget limitations and the uncommonness of hypocalcemia and hypercalcemia according to the

type of cancer of the study patients. 10. Increasing the age range of participants from 18-65 years to 18-70 years to provide the study sample size.

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20220609055113N1**

Registration date: **2022-09-04, 1401/06/13**

Registration timing: **prospective**

Last update: **2023-11-08, 1402/08/17**

Update count: **2**

#### Registration date

2022-09-04, 1401/06/13

#### Registrant information

##### Name

Reyhaneh Entezari heravi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3765 8488

##### Email address

r.entezari98@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-03-08, 1401/12/17

#### Expected recruitment end date

2024-03-08, 1402/12/18

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of the effect of serum vitamin D levels on anxiety and depression in patients with colorectal adenocarcinoma

#### Public title

"Effect of vitamin D on anxiety and depression of patients with colorectal cancer"

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Ability to read and write in Persian Ability to answer questionnaire questions

##### Exclusion criteria:

Complicated diabetes or hypertension History of visiting a psychiatrist or psychologist in the last 6 months or taking psychotropic drugs in the last 6 months Pregnancy Breastfeeding Taking vitamin D or vitamin D3 analogs in the last 3 months Vitamin D serum level more than 100 ng/ml

#### Age

From **18 years** old to **70 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

No information

#### Sample size

Target sample size: **45**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Islamic Azad University of Mashhad Medical Sciences Branch

##### Street address

NO. 181 , Resalat 7., Faramarz Abbasi 3., Faramarz Abbasi blvd.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9196111111

#### Approval date

2022-08-15, 1401/05/24

#### Ethics committee reference number

IR.IAU.MSHD.REC.1401.107

## Health conditions studied

### 1

#### Description of health condition studied

Anxiety

#### ICD-10 code

F41.9

#### ICD-10 code description

Anxiety disorder, unspecified

### 2

#### Description of health condition studied

Depression

#### ICD-10 code

F32.9

**ICD-10 code description**

Major depressive disorder, single episode, unspecified

**Primary outcomes**

**1**

**Description**

Depression score in Zung questionnaire

**Timepoint**

Before starting intervention, 90 days after starting to take cholecalciferol

**Method of measurement**

Zung Self-Rating Depression Scale questionnaire

**2**

**Description**

Anxiety score in Zung questionnaire

**Timepoint**

Before starting intervention, 90 days after starting to take cholecalciferol

**Method of measurement**

Zung Self-Rating Depression Scale questionnaire

**3**

**Description**

Serum level of 25-hydroxy vitamin D3

**Timepoint**

Before starting the intervention and 90 days after starting cholecalciferol

**Method of measurement**

enzyme-linked immunosorbent assay

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

The first intervention group: patients with a serum level of 25-hydroxyvitamin D3 less than 12 ng/ml receive 8 pearls of 50000 units of cholecalciferol from Zahravi Pharmaceutical Company one pearl weekly for 8 week and then 30 Tabs of 1000 units of cholecalciferol from Omid parsina damavand pharmaceutical company, daily for 24 days.

**Category**

Treatment - Drugs

**2**

**Description**

The second intervention group: patients with a serum level of 25-hydroxyvitamin D3 of 12-20 ng/ml receive a total of 90 Tabs of 1000 units of cholecalciferol from Omid parsina damavand pharmaceutical company, one pearl daily for 90 days.

**Category**

Treatment - Drugs

**3**

**Description**

The third intervention group: patients with a serum level of 25-hydroxyvitamin D3 of 20-30 ng/ml will receive a total of 60 pearls of 1000 units of cholecalciferol from Omid parsina damavand pharmaceutical company according to following command: Two days one pearl daily and then one day off for 3 months.

**Category**

Treatment - Drugs

**4**

**Description**

The fourth intervention group: patients with a serum level of 25-hydroxyvitamin D3 above 30 ng/ml will receive a total of 30 pearls of 1000 units of cholecalciferol from Omid parsina damavand pharmaceutical company, one pearl every 3 days for 3 months.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Reza Radiotherapy and Oncology Center

**Full name of responsible person**

Mahdieh Dayani

**Street address**

Reza Radiotherapy and Oncology Center, 19 Rafsanjani St., Haftom Azar Sq., Rafsanjani Hwy., International Fair Blvd., Mashhad, IRAN

**City**

Mashhad

**Province**

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**Postal code**

9184166759

**Phone**

+98 51 3500 8000

**Fax**

+98 51 3522 5671

**Email**

Info@rroc.ir

**Web page address**

<https://www.rroc.ir/>

**2**

**Recruitment center**

**Name of recruitment center**

22 Bahman Charitable Hospital

**Full name of responsible person**

Mitra Khazaei

**Street address**

22 Bahman Charitable Hospital, 39 Shahid Baba  
Nazar ST, Shahid Baba Nazar HWY, Tolloab QTR,  
Mashhad, Khorasan Razavi Province

**City**

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**Province**

Razavi Khorasan

**Postal code**

19156

**Phone**

+98 51 3259 5515

**Fax**

**Email**

22bahmanhospital@gmail.com

**Web page address**

<http://22bahman.mshdiau.ac.ir/fa/>

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Vahid Pouresmaeil

**Street address**

Faculty of Medicine, Azad University of Mashhad, 14th  
Imam Khomeini St., 14th Imam Khomeini St., Imam  
Khomeini Blvd.

**City**

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**Province**

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**Postal code**

9133735971

**Phone**

+98 51 3225 0041

**Email**

v.pouresmaeil@mshdiau.ac.ir

**Web page address**

<https://mashdms.iau.ir/>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

No

**Title of funding source**

Islamic Azad university, Mashhad medical science  
branch, Dr. Mohammad shahinfar medical school

**Proportion provided by this source**

1

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

### 2

**Sponsor**

**Name of organization / entity**

Zahravi Pharmaceutical Company

**Full name of responsible person**

Farhad Kiafar

**Street address**

No. 23, Darou paksh Ave, 18th km Tehran-karaj  
Makhsous Road, Alborz- Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1397116441

**Phone**

+98 21 4499 1893

**Email**

info@zahravipharma.com

**Web page address**

<http://www.zahravi.com/>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

No

**Title of funding source**

Zahravi Pharmaceutical Company

**Proportion provided by this source**

1

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Other

### 3

**Sponsor**

**Name of organization / entity**

Reza Radiotherapy and Oncology Center

**Full name of responsible person**

Mahdieh Dayani

**Street address**

Reza Radiotherapy and Oncology Center, 19  
Rafsanjani St., Haftom Azar Sq., Rafsanjani Hwy.,  
International Fair Blvd., Mashhad, IRAN

**City**

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**Province**

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**Postal code**

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**Phone**

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**Web page address**

<https://www.rroc.ir/>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Reza Radiotherapy and Oncology Center

**Proportion provided by this source**

1

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Other

**4**

**Sponsor**

**Name of organization / entity**

Omid parsina damavand pharmaceutical company

**Full name of responsible person**

Hamid reza Ali asgari

**Street address**

No. 21, West 12 Alley, Ahmed Qasir St., Argentina Square, Tehran, Tehran

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**Province**

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**Email**

info@opdpharma.com

**Web page address**

<https://www.opdpharma.com/>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Omid parsina damavand pharmaceutical company

**Proportion provided by this source**

1

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Other

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Reyhaneh Entezari heravi

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Unit 181, resalat, 7th ALLEY ,No. 3, Faramarz abbasi Ave, Faramarz abbasi Blvd, mashhad city

**City**

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**Email**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Reyhaneh Entezari heravi

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Unit 181, resalat, 7th ALLEY ,No. 3, Faramarz abbasi Ave, Faramarz abbasi Blvd, mashhad city

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

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**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Unit 181, resalat, 7th ALLEY ,No. 3, Faramarz abbasi Ave, Faramarz abbasi Blvd, mashhad city

**City**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

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

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

Only part of the data can be shared, such as information about the main outcome or the like.

**When the data will become available and for how long**

The access period starts 6 months after the results are published.

**To whom data/document is available**

It will be available only to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

Based on the criteria of the Ministry of Health, Treatment and Medical Education about clinical trial studies.

**From where data/document is obtainable**

E-mail: r.entezari.iaum@gmail.com

**What processes are involved for a request to access data/document**

After obtaining permission from the supervisor, the information will be sent by email.

**Comments**