

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 Porsina 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 Porsina 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

Razavi Khorasan

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, Tollab QTR,
Mashhad, Khorasan Razavi Province

City

Mashhad

Province

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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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9133735971

Phone

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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.,
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Email

Info@rroc.ir

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

City

Tehran

Province

Tehran

Postal code

1514758511

Phone

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+98 21 8604 3485

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

Mashhad

Province

Razavi Khorasan

Postal code

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Email

r.entezari98@gmail.com

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

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Person responsible for updating data

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

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Fax**Email**

r.entezari98@gmail.com

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