

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Evaluation of the effect of vitamin D on anxiety and depression in patients with esophageal cancer

#### Protocol summary

##### Study aim

Evaluation of the effect of vitamin D on anxiety and depression in patients with esophageal cancer

##### Design

A 4-arm clinical trial with parallel groups without randomization. No blinding with before and after design, without control group on 30 patients will be done

##### Settings and conduct

In this study, 30 new cases of esophageal cancer were referred. They will be admitted to the Reza Radiotherapy Center based on the criteria. Pearls of 5000 units of cholecalciferol of Zahravai pharmaceutical company according to the amount of serum 25OHD3 of the intervention groups according to the instructions. It is given below: deficiency group: daily, deficiency: every 5 days, borderline: every 7 days, sufficient: every 10 days. Serum level of 25OHD3 in the central laboratory University of Mashhad Jahad on enzyme-linked adsorbent immunoassay method will be measured. Patients before and after the intervention questionnaires Anxiety and depression fill Zung and 25hydroxyvitamin D3. Their serum is measured monthly.

##### Participants/Inclusion and exclusion criteria

**Inclusion:** At least 6 months passed since the diagnosis of esophageal cancer. Above 18 y. Ability to read and write. Ability to answer questionnaire. Ability to swallow oral medication. **Exclusion:** Previous psychiatric history. Taking psychiatric drugs in the last 6 months. History of drug abuse before cancer. Pregnancy or intention to pregnancy. Breastfeeding. Taking vitD in the last 3 months. Occurrence of any major stressful event after the start of the study

##### Intervention groups

Administration of 50000U of vitamin D pearls weekly at a serum level below 12ng/ml, every 10 days at a serum level of 12-20, every 14 days at a serum level of 20-30, monthly at a serum level above 30

##### Main outcome variables

Zung anxiety test before and after study Zung

depression test before and after study Serum level of 25 hydroxyvitamin D before and after study

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220731055593N1**

Registration date: **2023-01-07, 1401/10/17**

Registration timing: **prospective**

Last update: **2023-01-07, 1401/10/17**

Update count: **0**

##### Registration date

2023-01-07, 1401/10/17

##### Registrant information

##### Name

Masume Esmail Pour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 915 205 4542

##### Email address

masumesp@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-10, 1401/10/20

##### Expected recruitment end date

2023-05-19, 1402/02/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of vitamin D on anxiety and depression in patients with esophageal cancer

**Public title**

The effect of vitamin D on anxiety and depression in patients with esophageal cancer

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Esophageal cancer diagnosed at least 6 months ago Age above 18years Ability to read and write Ability to swallow oral medication

**Exclusion criteria:**

Pregnancy Breastfeeding Past psychological history History of drug abuse before cancer

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**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 Mashhad Islamic Azad University

**Street address**

Shahid Chamran Ave.Chamran15

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137635567

**Approval date**

2022-06-29, 1401/04/08

**Ethics committee reference number**

IR.IAU.MSHD.REC.1401.058

**Health conditions studied****1****Description of health condition studied**

Depression

**ICD-10 code**

F32

**ICD-10 code description**

Major depressive disorder, single episode

**2****Description of health condition studied**

Anxiety

**ICD-10 code**

F06.4

**ICD-10 code description**

Anxiety disorder due to known physiological condition

**Primary outcomes****1****Description**

Serum vitamin d3

**Timepoint**

Before - 3weeks after

**Method of measurement**

Serum vitamin d3

**2****Description**

Depression

**Timepoint**

Before-after

**Method of measurement**

Zung questionnaire

**3****Description**

Anxiety

**Timepoint**

Before-after

**Method of measurement**

Zung questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

First Intervention group:Weekly prescription of vitamin D  
50,000 units

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Reza Radiotherapy & Oncology Center

**Full name of responsible person**

Masume Esmail Pour Toroghi

**Street address**

Northern khayam 46.,shokri Blvd.,4th shokri.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9196747386

**Phone**

+98 915 205 4542

**Email**

masumesp@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Tooraj Zandbaf

**Street address**

Bazarche Sarab, No.Imam Khomeini 14.,Dr.Shahinfar  
Medical Faculty Islamic Azad University Of Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9187147578

**Phone**

+98 915 511 4523

**Email**

tooraj.zandbaf@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

100

**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

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Masume Esmail Pour Toroghi

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Northern khayam 46.,shokri Blvd.,4th shokri.

**City**

Mashhad

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**Contact**

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**Email**

masumesp@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Masume Esmaeil Pour

**Position**

Medical Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Khayam Ave 46, shokri Blvd 4, Khayam apartment

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9196747386

**Phone**

+98 915 205 4542

**Email**

masumesp@yahoo.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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

The original information cannot be shared, but the coded data is in the possession of the responsible Masume Esmaeil Pour.

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

The access period starts 12months after the results are published

**To whom data/document is available**

Academic institutions and researchers

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

Medical students

**From where data/document is obtainable**

The information and data are at the disposal of Masume Esmaeil Pour, the person responsible of the project, and you can contact the following email address: masumesp@yahoo.com

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

After conducting the intervention and reviewing the data and results of the research, almost 1 year after the publication of the results, the data are accessible

**Comments**