

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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Tooraj Zandbaf

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Bazarche Sarab, No.Imam Khomeini 14.,Dr.Shahinfar
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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

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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

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