

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of vitamin D supplementation on the treatment of patients with head and neck Squamous-Cell Carcinoma (SCC)

Protocol summary

Study aim

Evaluation of vitamin D supplementation on treatment results of patients with head and neck Squamous-Cell Carcinoma

Design

The clinical trial study has a controlled group, parallel-group, triple-blind, randomized, phase 3 clinical trial on 110 patients. Coin the Flip method was used for randomization.

Settings and conduct

This study will be conducted from May 2022 to November 2023 at Shafa Hospital in Kerman on all patients with squamous cell cancer. Patients are divided into two intervention and control groups by random allocation and using the coin toss method. Vitamin D is given to the intervention group and a placebo to the control group for 3 months. Then the patients are subjected to surgery, chemotherapy, radiotherapy, or a combination of these treatments and the rate of survival, recurrence, or response to the treatment is checked within a period of 1.5 years. Patients, researcher, and analysts are blind to the type of treatment.

Participants/Inclusion and exclusion criteria

The inclusion criteria include: 1- Histopathological proven head and neck squamous cell cancer and age 20 to 75 years. Exclusion criteria include: 1- previous use of vitamin D supplements 2- history of previous chemoradiotherapy 3- sensitivity to vitamin D supplements 4- the presence of metastasis 5- failure to complete the standard treatment protocol.

Intervention groups

The intervention group will be given vitamin D supplements at a dose of 2000 units per day and the control group will be given a placebo for three months.

Main outcome variables

Survival rate, recurrence, or response to treatment

General information

Reason for update

Acronym

Squamous-Cell Carcinoma (SCC)

IRCT registration information

IRCT registration number: **IRCT20230926059515N1**

Registration date: **2023-10-07, 1402/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-07, 1402/07/15**

Update count: **0**

Registration date

2023-10-07, 1402/07/15

Registrant information

Name

Mohammad Ali Damghani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3211 5780

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vitamin D supplementation on the treatment of patients with head and neck Squamous-Cell Carcinoma (SCC)

Public title

The effect of vitamin D supplementation on the treatment of head and neck cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with histopathologically proven head and neck squamous cell carcinoma Age 20 to 75 years

Exclusion criteria:

Previous use of vitamin D supplements History of previous chemoradiotherapy Allergy to vitamin D supplements The presence of metastasis Failure to complete the standard treatment protocol

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided into intervention and control groups using simple random allocation. Coin the Flip method was used for randomization. This method is usually used to create a random sequence in two-group experiments. In this study, the milk intervention group and the line control group were considered. Based on the desired sample size, a coin is tossed and people are divided into two groups by random allocation.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patients are unaware of the medicine they are receiving, and the control group is given a placebo. The complete response rate and the partial response rate to the treatment are checked by the researcher who does not know the type of treatment received by the patients. The coded variables are compared between the intervention and control groups by an analyst who does not know the type of treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway,

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2022-04-28, 1401/02/08

Ethics committee reference number

IR.KMU.AH.REC.1401.021

Health conditions studied

1

Description of health condition studied

Head and Neck Squamous-Cell Carcinoma

ICD-10 code

C49.0

ICD-10 code description

Malignant neoplasm of connective and soft tissue of head, face and neck

Primary outcomes

1

Description

Tumor recurrence through clinical examination and imaging: Tumor recurrence in the primary site of the tumor underwent surgery, tumor recurrence in a place other than the primary tumor site, such as the involvement of other organs than the head and neck

Timepoint

1.5 years

Method of measurement

Clinical examination or imaging if necessary

Secondary outcomes

1

Description

Response to chemoradiotherapy by clinical examination and imaging: tumor volume reduced by less than 50% of the initial amount: no response, tumor volume reduced by more than 50% of the initial amount: partial response,

no residual tumor: complete answer
Timepoint
1.5 year
Method of measurement
Clinical examination or imaging if necessary

Intervention groups

1
Description
The intervention group was supplemented with vitamin D (manufactured by Ariafarmed Peshgaman Salamat Pharmaceutical Company) at a dose of 2000 units per day and the control group (second) received placebo for three months.
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Shafa Hospital, Kerman
Full name of responsible person
Mohammad Ali Damghani
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Sponsors / Funding sources

1
Sponsor
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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
Kerman 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
Kerman University of Medical Sciences
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Niloofer Mohammadi
Position
Student
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Medical doctor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the publication of the results in the form of an article, there is no need to publish the details of the data

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information related to the main outcome of the study will be shared

When the data will become available and for how long

The access period starts 6 months after publishing the results

To whom data/document is available

Researchers to reanalyze the data

Under which criteria data/document could be used

Reviewers of scientific journals before publishing the article

From where data/document is obtainable

Corresponding author Mohammad Ali Damghani
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nmohammadi13@yahoo.com

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

Request with sufficient reasons by email Review and consultation of the research team The decision for data presentation

Comments