

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of the effect of different doses of vitamin D on the prognosis of patients after carpal tunnel syndrome syndrome

Protocol summary

Study aim

The aim of this study was to evaluate the effect of vitamin D in the treatment of patients after carpal tunnel syndrome surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 on 105 patients. Balanced block randomization method was used for randomization. In this method, sextuple blocks were used for random placement of participants in the study.

Settings and conduct

The study was performed in the orthopedic ward of Golestan and Imam Khomeini hospitals in Ahvaz. Patients were divided into three groups. The patients in the first group received 1000 units of vitamin D daily, the patients in the second group received 2,000 units per week for 2-3 weeks, and then 3,000 units of vitamin D per month. The third group of patients did not receive any vitamin D supplementation. Blinding was performed without informing the patient and the therapist about the type of drug prescribed (double-blind).

Participants/Inclusion and exclusion criteria

Carpal tunnel surgery

Intervention groups

Patients were divided into three groups. The patients in the first group received 1000 units of oral vitamin D daily, the patients in the second group received 2,000 units per week for 2-3 weeks, and then 3,000 units of oral vitamin D per month. The third group of patients did not receive any vitamin D supplementation.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180313039085N2**

Registration date: **2021-06-15, 1400/03/25**

Registration timing: **retrospective**

Last update: **2021-06-15, 1400/03/25**

Update count: **0**

Registration date

2021-06-15, 1400/03/25

Registrant information

Name

Tayeb Ramim

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6683 0007

Email address

tramim@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

2020-03-20, 1399/01/01

Actual recruitment end date

2021-05-22, 1400/03/01

Trial completion date

2021-05-22, 1400/03/01

Scientific title

Evaluation of the effect of different doses of vitamin D on the prognosis of patients after carpal tunnel syndrome syndrome

Public title

The effect of vitamin D in improving carpal tunnel

syndrome after surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Carpal tunnel release surgery

Exclusion criteria:

Patients' unwillingness to participate in the study

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **105**

Actual sample size reached: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced block randomization method was used for randomization. In this method, sextuple blocks were used for random placement of participants in the study.

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

Research Ethics Committees of Golestan Hospital

Street address

No. 10, West Azadi Ave.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2020-10-28, 1399/08/07

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.109

Health conditions studied

1

Description of health condition studied

Carpal Tunnel Syndrome

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes

1

Description

Pain

Timepoint

At the beginning of the study (before the intervention) and 6 months after vitamin D administration

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group I: The treatment involves the administration of an oral vitamin D pill. One tablet of 1000 units per day was prescribed for a period of six months. Its chemical composition is cholecalciferol, also known as vitamin D3. This drug is a dietary supplement that is produced in doses of 1000 units and 50,000 units by Ramofarmine Pharmaceutical Company. This drug in a dose of 1000 units can be taken daily and orally. It can be consumed in a dose of 50,000 units weekly and monthly.

Category

Treatment - Drugs

2

Description

Intervention group II: The treatment involves the administration of an oral vitamin D pill. One 50,000-unit vitamin D tablet was administered weekly for 4-6 weeks and then monthly for six months. Its chemical composition is calciferol, also known as vitamin D3. This drug is a dietary supplement that is produced in doses of 1000 units and 50,000 units by Ramofarmine Pharmaceutical Company. This drug in a dose of 1000 units can be taken daily and orally. It can be consumed in a dose of 50,000 units weekly and monthly.

Category

Treatment - Drugs

3

Description

Control group: Not receiving medication

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan hospital

Full name of responsible person

Karim Nourizadeh

Street address

No. 10, Golestan Ave.

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Web page address

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Aghdam

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Karim Nourizadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Karim Nourizadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Karim Nourizadeh

Position

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Latest degree

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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

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not 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

Article

When the data will become available and for how long

One year later

To whom data/document is available

All

Under which criteria data/document could be used

Published

From where data/document is obtainable

Data bank

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

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