

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The Effect of Vitamin D on the Treatment of Patients with Chronic Musculoskeletal Pain with Serum Vitamin D Deficiency

Protocol summary

Study aim

The effect of vitamin D on the control of chronic Musculoskeletal pain.

Design

Patients will be divided into two groups of 40 individuals in pairs, without randomization or blinding. The first group will receive 500 mg of naproxen daily in a single dose and the second group will receive a 300,000 unit intramuscular injection of naproxen every two weeks. Patients will be evaluated after 10 weeks and their pain levels will be measured by the NRS questionnaire.

Settings and conduct

A study will be conducted to determine the effect of vitamin D on chronic musculoskeletal pain in Fatemi Hospital of Ardabil.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients included in the study have chronic muscle pain and vitamin D levels are less than 30 ng / dl and are indicated for naproxen intake.

Exclusion criteria: Having underlying disease such as diabetes, cancer, rheumatoid arthritis

Intervention groups

Patients will be randomly divided into two groups of 40 each. The first group will receive 500 mg of naproxen daily in a single dose and the second group will receive a 300,000 unit intramuscular injection of naproxen every two weeks.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191019045153N1**

Registration date: **2019-12-07, 1398/09/16**

Registration timing: **retrospective**

Last update: **2019-12-07, 1398/09/16**

Update count: **0**

Registration date

2019-12-07, 1398/09/16

Registrant information

Name

Aydin Arabzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

z.pouaziz@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Vitamin D on the Treatment of Patients with Chronic Musculoskeletal Pain with Serum Vitamin D Deficiency

Public title

The Effect of Vitamin D on the Treatment of Patients with Chronic Musculoskeletal Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 15 to 45years History of Chronic Pain
Musculoskeletal Pain Low level of vitamin D, less than 30
n / ml

Exclusion criteria:

Having underlying diseases like diabetes, cancer,
rheumatologic disease

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

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 Ardabil University of Medical
Sciences

Street address

No. 1, Daneshgah Ave

City

Ardabil

Province

Ardabil

Postal code

5613843791

Approval date

2019-10-26, 1398/08/04

Ethics committee reference number

IR.ARUMS.REC.1398.401

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

Musculoskeletal Pain

ICD-10 code

M79.6

ICD-10 code description

Pain in limb, hand, foot, fingers and toes

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

Pain

Timepoint

At baseline and then 10 weeks after treatment

Method of measurement

NRS (numerical rating scale) questionnaire

Secondary outcomes

empty

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

Intervention group 1: This group includes 40 patients
with chronic musculoskeletal pain who have vitamin D
levels less than 30 ng / ml. These patients will receive
500 mg of oral naproxen daily. The pill will be a single
daily dose of Tehran medicine.

Category

Treatment - Drugs

2**Description**

Intervention group2: This group includes 40 patients with
chronic musculoskeletal pain who have vitamin D levels
less than 30 ng / ml. These patients will receive 500 mg
oral naproxen daily and a 300,000 unit dose of vitamin D
every two weeks. The tablets will be supplied in a single
daily dose and manufactured by Caspian Company's
Vitamin D and Ampoule Vitamin D tablets and will be
given by injection.

Category

Treatment - Drugs

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

Fatemi hospital

Full name of responsible person

Zahra Pouraziz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Parvaneh Naftchi

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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

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Aydin Arabzadeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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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

Undecided - It is not yet known if there will be 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 questionnaires will be made available anonymously and with a file number.

When the data will become available and for how long

پس از اتمام مطالعه

To whom data/document is available

University professors

Under which criteria data/document could be used

In order to find out how to work in SPSS file, anonymous questionnaires will only be available with file number.

From where data/document is obtainable

Contact Dr. Aydin Arabzadeh.

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

Information is available after contacting Dr. Vahid Adiban and University approval.

Comments