

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison between the effect of oral and intravenous vitamin D3 on statin-induced myopathy level :Randomized Controlled Trial

Protocol summary

Study aim

Comparison of oral and intravenous vitamin D3 in reducing statin myopathy

Design

Phase 2 of the clinical trial has a control group that is community-oriented and pragmatic. With parallel groups. One blind and randomized sample of 50 people

Settings and conduct

This study is a randomized single-blind clinical trial of patients with statin-induced myopathy in Golestan Hospital. written and oral consent will be received from all of the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.The presence of symptoms of myalgia in the 60 days of initiation or increase in the dose of statins. 2. Age of patients aged 18 to 65 years. 3. Decrease vitamin D (25OH Vitamin D3) levels from normal range (<32ng / ml). Exclusion criteria: 1. Company's dissatisfaction with the study. 2. Failure to study. 3. Drinking alcohol or drugs. 4. Collagen disease, vascular, coagulopathy, genetic, cerebrovascular disease. 5. Creatine kinase level above 300U / L, indicating fibromyalgia. 6. The patient is not able to use Pearl vitamin D3 or a tendency to inject a drug. 7. The history and evidence of examination indicate trauma in the organs.

Intervention groups

. Control group: For patients, 50000 units of vitamin D (ergocalciferol) are administered orally once a week for 8 weeks. Intervention group: For patients, two doses of IU 300,000 are given at intervals of one month for 8 weeks.

Main outcome variables

For all patients, the levels of vitamin D, muscle creatine phosphokinase (CPK), serum Ca level and serum P levels are measured at the beginning of the study and at the end of the study (after 8 weeks). A 10-cm visual analogue scale (VAS) questionnaire is used to assess pain in patients at the beginning of the study and at the end of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180422039379N1**

Registration date: **2018-06-05, 1397/03/15**

Registration timing: **retrospective**

Last update: **2018-06-05, 1397/03/15**

Update count: **0**

Registration date

2018-06-05, 1397/03/15

Registrant information

Name

Ahmad Sadinpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3554 2180

Email address

sadinpoor.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-22, 1396/07/30

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

2017-10-22, 1396/07/30

Actual recruitment end date

2017-12-21, 1396/09/30

Trial completion date

empty

Scientific title

Comparison between the effect of oral and intravenous vitamin D3 on statin-induced myopathy level
:Randomized Controlled Trial

Public title

Evaluation of oral and injection vitamin D3 on reducing statin-induced myopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. There are symptoms of myalgia with statins 2. Age of patients aged 18 to 65 years. 3. Lower levels of vitamin D (25OH Vitamin D3) from normal range (<32ng / ml).

Exclusion criteria:

1. Patient does not provide consent. 2. Failure to complete the study 3. Age under 18 and over 65 years. 4. Alcohol or substance abuse. 5. Collagen disease, vascular, coagulopathy, genetic, cerebrovascular disease. 6. Creatine kinase level above 300U / L, indicating fibromyalgia. 7. The patient is not able to use Pearl vitamin D3 or a tendency to inject a drug. 8. The history and evidence of examination indicate trauma in the organs.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **43**

Randomization (investigator's opinion)

Randomized

Randomization description

The permutational block method is used for randomization.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study the statistical analyzer does not know which patients are present in the group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz-Naderi Street-Corner, North Kathanafah Avenue-Dr. Zarger Nejad Pharmacy

City

Ahvaz

Province

Khouzestan

Postal code

6193944166

Approval date

2017-10-13, 1396/07/21

Ethics committee reference number

IR.AJUMS.REC.1396.527

Health conditions studied

1

Description of health condition studied

Statins myopathy

ICD-10 code

G72.0

ICD-10 code description

Drug-induced myopathy

Primary outcomes

1

Description

"Measuring serum level of vitamin D3"

Timepoint

"Measuring serum level of vitamin D3 at the beginning of the study (before the intervention) and at the end of the study (8 weeks after starting vitamin D)"

Method of measurement

Serum levels of vitamin D were measured using ELISA method.

2

Description

"Measuring the severity of myopathy pain"

Timepoint

"Measuring the severity of pain at the beginning of the study (before the intervention) and 8 weeks after taking vitamin D"

Method of measurement

"Visual Analogue Scale (VAS)"

Secondary outcomes

empty

Intervention groups

1

Description

Control group: For all patients Pearl, 50,000 units of

vitamin D (Zahravi Company) will be given orally once a week for 8 weeks. "

Category

Treatment - Drugs

2**Description**

Intervention group: For all patients, 300,000 units of vitamin D (Caspian) will be given once a month for 2 months. "

Category

Treatment - Drugs

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

Ahvaz Golestan Hospital

Full name of responsible person

Ahmad sadinpour

Street address

Ahvaz Golestan Hospital

City

Ahvaz

Province

Khuzestan

Postal code

6193944166

Phone

+98 61 3223 3475

Email

sadinpourahmad@gmail.com

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

Ahvaz University of Medical Sciences

Full name of responsible person

Ahmad sadinpour

Street address

Ahvaz / Golestan / Jundishapur University / School of Pharmacy

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3373 8283

Email

sadinpourahmad@gmail.com

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

Reza ganji

Position

PHD

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Ahvaz, Golestan Blvd., Jundishapur University of Medical Sciences, Ahvaz, Iran.

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3373 8283

Email

Rg.pharm77@gmail.com

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

Ahvaz University of Medical Sciences

Full name of responsible person

Reza ganji

Position

Ph.D. in Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd

City

Ahvaz

Province

Khouzestan
Postal code
6135733184
Phone
+98 61 1373 8378
Email
Rg.pharm77@gmail.com

Khouzestan
Postal code
6193944166
Phone
+98 61 1373 8378
Email
sadinpourahmad@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ahmad sadinpour
Position
Pharmacy student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
Ahwaz University of Jundishapur. Faculty of Pharmacy
City
Ahvaz
Province

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

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

No - There is not 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