

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of vitamin D replacement therapy on the incidence of statin associated muscle complications

Protocol summary

Study aim

The effect of vitamin D replacement therapy on the incidence of statin-related muscle complications in patients who have been recently treated with statin

Design

A concealed, randomized, blinded, controlled clinical trial with a parallel group design of 78 patients, enrolled between October 2016 to February 2017, were followed up for at least three months

Settings and conduct

Seventy-eight patients admitted to Afshar Hospital in Yazd who had been diagnosed with acute coronary syndrome in the center since October 2016 to February 2017, were treated with atorvastatin and low levels of vitamin D were included. Medication and placebo are named by a person who does not have an intervention in the treatment, to drug 1 and drug 2. One of these two is randomly injected by a nurse who is unaware of the nature of the drugs (the drugs are prescribed by the first person). So that neither patients nor therapists are aware of prescription drugs

Participants/Inclusion and exclusion criteria

Entry conditions: All patients who have been recently treated with atorvastatin
No entry conditions: Previous history of statin use; Previous history of Vitamin D Supplement use; having musculoskeletal symptoms; history of musculoskeletal disease; history of thyroid disease

Intervention groups

In one group, the injection of 300,000 units of vitamin D was administered muscularly and into another, placebo (sterile water injection) was administered

Main outcome variables

Myalgia, increased creatine kinase, myopathy, rhabdomyolysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180513039645N1**

Registration date: **2018-07-16, 1397/04/25**

Registration timing: **retrospective**

Last update: **2018-07-16, 1397/04/25**

Update count: **0**

Registration date

2018-07-16, 1397/04/25

Registrant information

Name

Vahid Kabiri rad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3611 1357

Email address

kabiriradv2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-20, 1395/09/30

Expected recruitment end date

2017-05-21, 1396/02/31

Actual recruitment start date

2016-12-20, 1395/09/30

Actual recruitment end date

2017-05-21, 1396/02/31

Trial completion date

empty

Scientific title

The effect of vitamin D replacement therapy on the incidence of statin associated muscle complications

Public title

The effect of Vitamin D on the prevention of statin associated muscle complications

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who have been recently treated with atorvastatin

Exclusion criteria:

Previous history of statin use
Previous history of Vitamin D Supplement use
having musculoskeletal symptoms
history of musculoskeletal disease
history of thyroid disease

Age

From **30 years** old to **84 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

Actual sample size reached: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual, Using the random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

Medication and placebo are named by a person who does not have an intervention in the treatment, to drug 1 and drug 2. One of these two is randomly injected by a nurse who is unaware of the nature of the drugs (the drugs are prescribed by the first person). So that neither patients nor therapists are aware of prescription drugs.

Placebo

Used

Assignment

Parallel

Other design features

Pilot study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Faculty of Medicine, Shahid Sadoughi University of

Medical Sciences and Health Services; Professor Hesabi Blvd; Yazd Town

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2016-11-13, 1395/08/23

Ethics committee reference number

IR.SSU.MEDICINE.REC.1395.203

Health conditions studied

1

Description of health condition studied

Acute ischemic heart disease

ICD-10 code

I24.9

ICD-10 code description

Acute ischemic heart disease, unspecified

Primary outcomes

1

Description

Statin associated muscle symptom score

Timepoint

At the beginning of the study, 1, 2 and 3 months after the start of taking statin and administering vitamin D and placebo

Method of measurement

Statin associated Muscle Symptom Score Questionnaire

2

Description

Serum Creatine Kinase level

Timepoint

At the beginning of the study and 3 months later

Method of measurement

By the laboratory

Secondary outcomes

1

Description

Cholesterol

Timepoint

At the beginning of the study and 3 months later

Method of measurement

By the laboratory

2

Description

Fasting blood sugar

Timepoint

At the beginning of the study and 3 months later

Method of measurement

By the laboratory

Intervention groups

1

Description

Intervention group: : Vitamin D 3, 300,000 units; one dose; muscular

Category

Treatment - Drugs

2

Description

Control group: Sterile water ampule; 1mililiter; muscular

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Sadeq Afghan hospital

Full name of responsible person

Ali Pedarzade

Street address

Mohammad Sadeq Afghan hospital, Jomhoori Blvd;
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzayee

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Faculty of Medicine, Shahid Sadoughi University of
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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

Yazd 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

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Kabiri Rad

Position

Non-faculty specialist

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Full name of responsible person

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City**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available