

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical evaluation of the effects of Ascorbic acid on attenuation of the statin induced myopathy: a randomized double blinded placebo-controlled clinical trial

Protocol summary

Study aim

Clinical evaluation of the effects of vitamin C on attenuation of the statin induced myopathy

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 is performed on 40 patients and the RND() function of Excel software is used for randomization. Serum enzyme levels are measured 24 hours after exercise and they receive medication and placebo daily for two weeks. After 2 weeks, the serum levels of their enzymes are measured again 24 hours after exercise.

Settings and conduct

Randomized double blinded placebo-controlled trial

Participants/Inclusion and exclusion criteria

People between 80-30 years old; Patients undergoing exercise for cardiac rehabilitation; Daily intake of 40 mg atorvastatin; Maximum weight 80 kg; Non-pregnancy of women; The patient should not have severe peptic ulcer

Intervention groups

Daily consumption of two drug or plasebo for 14 days

Main outcome variables

Blood levels of creatine kinase, aldolase and lactate dehydrogenase enzymes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045356N2**

Registration date: **2021-04-18, 1400/01/29**

Registration timing: **prospective**

Last update: **2021-04-18, 1400/01/29**

Update count: **0**

Registration date

2021-04-18, 1400/01/29

Registrant information

Name

Mohsen Zabihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3865

Email address

mzabihi100@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of the effects of Ascorbic acid on attenuation of the statin induced myopathy: a randomized double blinded placebo-controlled clinical trial

Public title

evaluation of the effects of Ascorbic acid on attenuation of the statin induced myopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People between 80-30 years old Patients undergoing exercise for cardiac rehabilitation Daily intake of 40 mg of atorvastatin Maximum weight 80 kg Non-pregnancy of women The patient should not have severe peptic ulcer

Exclusion criteria:
Vitamin C intolerance Do not take medication for more than two consecutive days Do not take atorvastatin for more than two consecutive days The patient becomes pregnant

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is performed based on the RND function of Excel software and patients are divided into two groups A and B. The drug and placebo are uniform and coded in terms of the shape of the drug and the drug container, and the patient and the physician prescribing the drug and the evaluator do not know the composition and content of each drug container.

Blinding (investigator's opinion)
Double blinded

Blinding description
Different groups of drugs are placed in uniform and coded containers, and the prescribing physician and the evaluator do not know the composition and content of each drug container.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Alem sq.

City

Yazd

Province

Yazd

Postal code

8916978447

Approval date

2021-03-21, 1400/01/01

Ethics committee reference number

1111

Health conditions studied

1

Description of health condition studied

Myopathy

ICD-10 code

G72.0

ICD-10 code description

Drug-induced myopathy

Primary outcomes

1

Description

Creatine kinase, aldolase and lactate dehydrogenase levels

Timepoint

Evaluation of patient tests on days 1 and 14 of the intervention

Method of measurement

Patient blood test and measurement of creatine kinase, aldolase and lactate dehydrogenase using relevant kits

Secondary outcomes

empty

Intervention groups

1

Description

Includes 20 patients who are randomly selected based on the RND() function of Excel software. Patients receive two 500 mg of vitamin C capsules daily made by an Iranian pharmaceutical company for 14 days, and on days 1 and 14, 24 hours after cardiac rehabilitation exercise, using a blood test for creatine kinase, lactate dehydrogenase and aldolase enzymes are measured.

Category

Treatment - Drugs

2

Description

Includes 20 patients who are randomly selected based on the RND() function of Excel software. Patients receive two starch capsules daily for 14 days, and on days 1 and 14, 24 hours after cardiac rehabilitation exercise, using a blood test for creatine kinase, lactate dehydrogenase and aldolase enzymes are measured.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshar hospital

Full name of responsible person

Dr. Mohsen Zabihi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

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?

No

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

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mohsen Zabihi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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