Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Nov 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
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3820 3419
Email
mzabihi100@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Mohsen Mirzaie
Street address
Bahonar sq.
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3726 3733
Email
dvc.research@ssu.ac.ir

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
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
8915173149
Phone
+98 35 3820 3419
Email
mzabihi100@gmail.com

Person responsible for scientific 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
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
8915173149
Phone
+98 35 3820 3419
Email
mzabihi100@gmail.com

Person responsible for updating data

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
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
8915173149
Phone
+98 35 3820 3419
Email
mzabihi100@gmail.com

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