Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of the Effect of Coenzyme Q10 supplementation on inflammatory markers(high-sensitivity C-reactive protein, interleukin-6, and oxidative stress and increases antioxidant enzyme activity) in patients with COPD

Protocol summary

Study aim
Determination of the effect of COQ10 supplement on CRP inflammatory markers and oxidative stress in COPD patients

Design
Clinical trial with control group, with parallel group; Double blind, randomized

Settings and conduct
Valiasr Hospital of Birjand - South Khorasan This study is done in the valiasr hospital in Birjand, south khorasan province. 90 patients are randomly divided into 2 intervention and control groups. blood samples are taken from patients In the beginning of the study and the antioxidant serum level is measured before the treatment is started. Then the intervention is done for 6 weeks and blood samples are taken again. Antioxidant parameters will be measured by the Lab Technician. Of the birjand university of medical science. In this study the administrative steps are done by the lab technician and both the patients and the project executive will be uninformed of the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-subject is aged 18 or older 2- subject is not taking any Nutritional or medical supplements. 3- Subject provides written informed consent. Exclusion criteria: 1- Refusal to give informed consent 2- diagnosis of mellitus diabetes, PTE, CKD, CAD and bacterial pneumonia 3- taking any complementary medicines 4- diagnosis of COPD with current treatment of antioxidant medicine and supplements or any medicine that affects antioxidant storage and mitocondrial system 5- death of the subject during the test

Intervention groups
The intervention group consists of 45 patients with COPD recieving two 60mg CoQ10 pills. The control group consists of 45 patients with COPD recieving two pills containing starch..

Main outcome variables
Total anti oxidant FEV1 FEVC DPPD Hs-CRP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190618043934N1**
Registration date: **2019-08-26, 1398/06/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-26, 1398/06/04**
Update count: **0**

Registration date
2019-08-26, 1398/06/04

Registrant information

Name
Zabihullah Mohaghegh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 56 3232 3232

Email address
oabstudent@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-21, 1398/03/31

Expected recruitment end date
2019-09-22, 1398/06/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Effect of Coenzyme Q10 supplementation on inflammatory markers(high-sensitivity C-reactive protein, interleukin-6, and oxidative stress and increases antioxidant enzyme activity) in patients with COPD

Public title

Study of the effect of Coq10 on patients with shortness of breath

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

At least 18 years of age, no nutritional and pharmaceutical supplementation, and informed consent.

Exclusion criteria:

diagnosis of mellitus diabetes, PTE, CKD, CAD and bacterial pneumonia or taking any complementary medicines.Also diagnosis of COPD with current treatment of antioxidant medicine and supplements or any medicine that affects antioxidant storage and mitocondrial system.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

More than 1 sample in each individual

Number of samples in each individual: **2**

Befor and after from intervention

Randomization (investigator's opinion)

Randomized

Randomization description

Lottery method of Simple random sampling

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in the study administrative of the study

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Moallem BLV-ferdowsi ST

City

Birjand

Province

South Khorasan

Postal code

9717811674

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

ir.bums.REC.1397.189

Health conditions studied

1

Description of health condition studied

COPD Disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description

Serum levels of antioxidants in the serum of patients

Timepoint

Before the intervention placebo and 6 weeks after starting the Coq10 capsule

Method of measurement

thiobarbituric acid method

Secondary outcomes

1

Description

Serum levels of antioxidants in the serum of patients

Timepoint

6 weeks after taking the supplement or placebo

Method of measurement

thiobarbituric acid method

Intervention groups

1

Description

Intervention group: The intervention group will receive 2 tablets of 60 mg coccitone for 6 weeks each day.

Category

Treatment - Drugs

2

Description
Control group: The control group received 2 tablets of starch containing as a placebo for 6 days .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valieasr hospital
Full name of responsible person
Reza yaghobi marake
Street address
Molallem BLV-Ferdowsi ST
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr. tooba kazemi
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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
Birjand University of Medical Sciences
Proportion provided by this source
50
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
Birjand University of Medical Sciences
Full name of responsible person
Zabihullah mohaghegh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Student

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General Practitioner

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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
There is no need to publish individual patient information

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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
The demographic data of patients in general, along with the serum levels of antioxidants and other commonly used drugs, will be reported in general.

When the data will become available and for how long
After publishing the results as thesis And articleپژ

To whom data/document is available
Medical Researchers

Under which criteria data/document could be used
No

From where data/document is obtainable
Article or Thesis

What processes are involved for a request to access data/document
Patient personal information will not be shared with anyone.

Comments