

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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 mitochondrial system 5- death of the subject during the test

Intervention groups

The intervention group consists of 45 patients with COPD receiving two 60mg CoQ10 pills. The control group consists of 45 patients with COPD receiving 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)

Phone

+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 mitochondrial 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**
Before 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

City

Birjand

Province

South Khorasan

Postal code

9717811674

Phone

+98 56 3232 3232

Email

oabstudent@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. tooba kazemi

Street address

Ghaffari BLV

City

Birjand

Province

South Khorasan

Postal code

9717811674

Phone

+98 56 3238 1200

Email

oabstudent@gmail.com

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

Street address

Moallem BLV-Ferdowsi ST

City

Birjand

Province

South Khorasan

Postal code

9717811674

Phone

+98 56 3232 3232

Email

oabstudent@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. gholamreza mortazavimoghaddam

Position

science Committee

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Ghaffari BLV

City

Birjand

Province

South Khorasan

Postal code

9717811674

Phone

+98 56 3232 3232

Email

oabstudent@gmail.com

Person responsible for updating data

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

Street address

Moallem Blvd, Ferdowsi St.

City

Birjand

Province

South Khorasan

Postal code

9717811674

Phone

+98 56 3232 3232

Fax**Email**

oabstudent@gmail.com

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 article پز

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