

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of Conjugated linoleic acid supplemented diet on nutritional status, and oxidative stress in Chronic Obstructive Pulmonary Disease patients

Protocol summary

Summary

Objectives: Today, oxidative stress as a predisposing factor in the pathogenesis of Chronic Obstructive Pulmonary Disease is known, although the correlation between chronic obstructive pulmonary diseases with antioxidants remains unclear. **Design:** So this study was to evaluate the effect of conjugated linoleic acid (CLA), as an antioxidant, on serum level of malondialdehyde (MDA), matrix metalloproteinase 1 (MMP1), matrix metalloproteinase 2 (MMP2), Leptin, Sirtuin 1, Interleukin 6 and Interleukin-1 beta (IL1 β) as bio-marker for oxidative stress occurs. **Setting and conduct:** This double-blind prospective study on ninety cases of chronic obstructive pulmonary disease at the interval January 2015 to December 2015 in Imam Khomeini hospital in Ardebil is done. The provided forms containing demographic information, Chronic obstructive pulmonary disease Assessment Test (CAT), modified dyspnea scale (MMRC) and appetite questionnaire is completed. Then, spirometry and six-minute walk test is done. Then 3 cc of blood from patients to measure serum levels of Interleukin-1beta, malondialdehyde, matrix metalloproteinase 1 (MMP1), matrix metalloproteinase 2 (MMP2), Leptin, Sirtuin 1, Interleukin 6 and serum total antioxidant capacity is taken. **Participants** including major eligibility criteria: inclusion criteria include Chronic Obstructive Pulmonary Disease patients aged between 40-80; clinically stable disease with FEV1 less than 75% predict and exclusion criteria include female; any associated chronic diseases such as CAD and CKD...receiving any interacting drugs; abnormal chest x ray **Intervention:** The original drug (conjugated linoleic acid 3.2 g, soft gel 800mg four times in day) and placebo (soft gel four times in day) in equal numbers will be packed in similar package. Packets from one to ninety-numbered and randomly given to patients for six weeks. Six weeks after the intervention, again COPD Assessment Test (CAT), dyspnea scale (MMRC) and appetite completed questionnaires, spirometry and six-

minute walking test was performed for the second time. During the intervention, the patient closely for possible side effects and medication use are followed. Main outcome measures (variables): blood sampling is repeated for matrix metalloproteinase 1 (MMP1), matrix metalloproteinase 2 (MMP2), Leptin, malondialdehyde (MDA) and Interleukin-1 beta (IL1 β), Sirtuin 1, Interleukin 6 and total antioxidant capacity. Before entering the study, written informed consent was obtained from all patients

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080823559N1**

Registration date: **2015-09-27, 1394/07/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-27, 1394/07/05

Registrant information

Name

Somaieh Matin

Name of organization / entity

Ardabil University of Medicine Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical Sciences

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2015-12-30, 1394/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Conjugated linoleic acid supplemented diet on nutritional status, and oxidative stress in Chronic Obstructive Pulmonary Disease patients

Public title

Effect of Conjugated Linoleic Acid supplemented diet on oxidative stress in Chronic Obstructive Pulmonary Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Chronic Obstructive Pulmonary Disease patients aged between 40-80: clinically stable disease with FEV1 less than 75% predict. Exclusion criteria:female: any associated diseases such as CAD and CKD ...: receiving any interacting drugs: abnormal chest x ray

Age

From **40 years** old to **80 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ardabil University of Medicine Sciences Ethics committee

Street address

Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

City

Ardabil

Postal code

53141-56198

Approval date

2015-01-18, 1393/10/28

Ethics committee reference number

9116

Health conditions studied**1****Description of health condition studied**

Chronic Obstructive Pulmonary Disease

ICD-10 code

J40, J41,

ICD-10 code description

Chronic Lower Respiratory Diseases

Primary outcomes**1****Description**

malondialdehyde (MDA) serum level

Timepoint

At the beginning of study and 6 weeks after intervention

Method of measurement

Lab.

2**Description**

IL1 β serum level

Timepoint

At the beginning of study and 6 weeks after intervention

Method of measurement

Lab.

3**Description**

Total Antioxidan Capacity

Timepoint

At the beginning of study and 6 weeks after intervention

Method of measurement

Lab.

4

Description

matrix metalloproteinase 1 serum level(MMP1)

Timepoint

At the beginning of study and 6 weeks after intervention

Method of measurement

Lab.

5

Description

matrix metalloproteinase 2 (MMP2) serum level

Timepoint

At the beginning of study and 6 weeks after intervention

Method of measurement

Lab.

6

Description

Leptin serum level

Timepoint

At the beginning of study and 6 weeks after intervention

Method of measurement

Lab.

7

Description

Added at 2017-11-01: Sirtuin 1

Timepoint

Added at 2017-11-01: before and after intervention

Method of measurement

Added at 2017-11-01: ELISA

8

Description

Added at 2017-11-01: Interleukin 6

Timepoint

Added at 2017-11-01: At the beginning of study and 6 weeks after intervention

Method of measurement

Added at 2017-11-01: Lab

Secondary outcomes

1

Description

CLA side effects

Timepoint

At the beginning of study and 6 weeks after intervention

Method of measurement

patient

Intervention groups

1

Description

treatment intervention with conjugated linoleic acid

3.2 g(soft gel 800mg four times in day) for six weeks

Category

Treatment - Drugs

2

Description

Placebo soft gel four times in day for six weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Somaieh Matin

Street address

Imam Khomeini Hospital, Shahid Jeddi Street, Ardabil

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ardabil University of Medical Sciences

Full name of responsible person

Dr Shahram Habibzadeh

Street address

Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran

City

Ardabil

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Somaieh Matin

Position

Internal Medicine Resident

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Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty