

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Study of the effect of fortified whey drink with Vitamin C and Magnesium on nutritional status, quality of life, strength of muscle, oxidative stress, inflammation and pulmonary status in chronic obstructive pulmonary disease patients.

Protocol summary

Study aim

Determining the effect of fortified whey drink with Vitamin C and Magnesium on nutritional status, quality of life, strength of muscle, oxidative stress, inflammation and pulmonary status in chronic obstructive pulmonary disease patients who refer to clinical centers of Shiraz University of Medical Sciences in 2018-2019.

Design

randomized, parallel group trial with control and intervention groups with 23 patients in each group

Settings and conduct

The participants of this study will be selected from outpatients living in Shiraz with chronic obstructive pulmonary disease (COPD) referred to the clinical centers of Shiraz University of Medical Sciences based on the mentioned inclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Men over 50 years old with COPD disease in moderate and severe stages based on spirometry and FEV1 index - Moderate stage is at least 6 months of diagnosis. - Being malnourished based on FFMI
Exclusion criteria: - History of any acute Inflammatory , infectious, liver, kidney , rheumatoid arthritis, heart diseases and cancer - consumption of antioxidant (vitamin E, C,...) and protein supplements

Intervention groups

intervention group: receiving 220 ml of whey drink enriched with vitamin C and magnesium plus dietary recommendation per day control group: receiving daily dietary recommendation

Main outcome variables

oxidative stress, inflammatory markers, nutritional status, quality of life, strength of muscle, and pulmonary status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161119030975N2**

Registration date: **2018-12-29, 1397/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-29, 1397/10/08**

Update count: **0**

Registration date

2018-12-29, 1397/10/08

Registrant information

Name

afsaneh ahmadi

Name of organization / entity

shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1001

Email address

ahmadia@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of fortified whey drink with Vitamin C and Magnesium on nutritional status, quality of life, strength of muscle, oxidative stress, inflammation and pulmonary status in chronic obstructive pulmonary disease patients.

Public title

Evaluating the effect of whey enriched drink on the nutritional status of patients with chronic obstructive pulmonary disease

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Men over 50 years old Chronic Obstructive Pulmonary Disease (COPD) disease in moderate and severe stages based on spirometry and Forced Expiratory Volume 1 (FEV1) index at least 6 months after diagnose of the moderate stage of disease. being malnourished based on fat free mass index (FFMI)

Exclusion criteria:

History of any acute inflammatory, infectious, liver, kidney, rheumatoid arthritis, heart diseases and cancer consumption of antioxidant (vitamin E, C, ...) and protein supplements

Age

From 50 years old

Gender

Male

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: 46

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified block randomization, individual with using dice

Blinding (investigator's opinion)

Single blinded

Blinding description

The intervention group receives drinks at home

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

School of Nutrition and Food Sciences- Razi blvd- Shiraz

City

shiraz

Province

Fars

Postal code

7153675541

Approval date

2017-07-30, 1396/05/08

Ethics committee reference number

85.IR.SUMS.REC.1396

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

chronic obstructive pulmonary diseases

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

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

Inflammation

Timepoint

The First and End of the study

Method of measurement

Measuring Interleukin-6 and Tumor Necrosis Factor Alfa

Secondary outcomes**1****Description**

malnutrition

Timepoint

The First and End of the study

Method of measurement

FFMI

Intervention groups**1****Description**

intervention group: fortified whey drink with magnesium and vitamin C and dietary recommendation

Category

Prevention

2

Description

Control group: dietary recommendation

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical centers of Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hassan Eftekhari

Street address

Razi Blvd

City

shiraz

Province

Fars

Postal code

7153675541

Phone

+98 71 3725 1005

Email

h_eftekhari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hasan Eftekhari

Street address

Razi Blvd

City

shiraz

Province

Fars

Postal code

7153675541

Phone

+98 71 3725 1005

Email

h_eftekhari@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Afsane Ahmadi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Razi Blvd

City

shiraz

Province

Fars

Postal code

7153675541

Phone

+98 71 3725 1005

Email

ahmadia@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hasan Eftekhari

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Razi Blvd

City

Shiraz

Province

Fars

Postal code

7153675541

Phone

+98 71 3725 1005

Email

h_eftekhari@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Afsane Ahmadi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Razi Blvd

City

shiraz

Province

Fars

Postal code

7153675541

Phone

+98 71 3725 1005

Email

ahmadia@sums.ac.ir

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