Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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