Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Investigating the effect of nano-curcumin supplementation on ventilatory capacity, polmonary function indices and serum interleukin-6 of patients with stage 3 (severe) and 4 (very severe) chronic obstructive pulmonary disease

Protocol summary

Study aim
The effect of nano-curcumin supplementation on respiratory capacity and serum IL-6 level in patients with stages 3 and 4 of chronic obstructive pulmonary disease

Design
A randomized, controlled, parallel groups, double-blind, placebo-controlled clinical trial

Settings and conduct
In this study, 60 participants from among the patients with chronic obstructive pulmonary disease (COPD) in the pulmonary ward of Imam Khomeini Hospital in Urmia, who are in the third and fourth stages of COPD in terms of the severity of the disease and the type of treatment, will be selected by observing the inclusion and exclusion criteria and then will be randomly divided into intervention and control groups. The control group will receive their common medical treatment and the placebo and the intervention group will receive a nano-curcumin capsule containing 80 mg of curcumin in the form of nano micelles daily in addition to their common medical treatment. Food intake, physical activity and the amount of tobacco consumption will be obtained by a questionnaire before and after the intervention. Also, the respiratory capacity, indicators related to the adequacy of the patients' lung function and the serum levels of interleukin 6 will be measured using spirometry and ELISA, respectively, before and after the intervention.

Participants/Inclusion and exclusion criteria
Adult age range (18-65 years). Smokers who have been smoking for at least 10 years. Confirmation of chronic pulmonary obstruction based on GOLD index.The patient has stages 3 and 4 of chronic pulmonary obstruction

Intervention groups
The intervention group will receive an oral nano-curcumin capsule containing 80 mg curcumin as a nano micelle daily for 3 months. The control group will receive one placebo capsule daily (consisting of polysorbate, propylene glycol and distilled water) for 3 months.

Main outcome variables
FEV1/FEC; Interleukin-6

General information

Reason for update
To update the dosage of the supplement used and the variables studied

Acronym

IRCT registration information
IRCT registration number: **IRCT20191222045853N1**
Registration date: **2020-02-06, 1398/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-31, 1402/08/09**
Update count: **2**

Registration date
2020-02-06, 1398/11/17

Registrant information

Name
Mahdieh Zareie

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

2020-01-21, 1398/11/01

Actual recruitment end date

2020-09-22, 1399/07/01

Trial completion date

2020-09-22, 1399/07/01

Scientific title

Investigating the effect of nano-curcumin supplementation on ventilatory capacity, polmonary function indices and serum interleukin-6 of patients with stage 3 (severe) and 4 (very severe) chronic obstructive pulmonary disease

Public title

The effects of nano-curcumin on obstructive pulmonary disease patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

• Adult age range (18-65 years). Smokers who have been smoking for at least 10 years. Confirmation of chronic obstructive pulmonary disease according to GOLD criteria. The patient has stages 3 and 4 of chronic pulmonary obstruction.

Exclusion criteria:

Patient with gallstones Infectious diseases Gastrointestinal problems such as malabsorption Other chronic diseases (such as cancer, kidney disease, diabetes, etc.). Long-term use of corticosteroid drugs and compounds, ie, more than 10 days of corticosteroid use per year. Use of any anticoagulant drugs such as heparin, aspirin, clopidogrel, dipyridamole, warfarin and ticlopidine.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Actual sample size reached: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the block randomization method. We have two case and control groups (C and T) that will have 6 models using 4 blocks (TTCC, TCTC, TCCT, CCTT, CTCT, CTTC). Subjects randomly will be assigned to case and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Using coding on supplements

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-12-07, 1397/09/16

Ethics committee reference number

IR.UMSU.REC.1398.295

Health conditions studied

1

Description of health condition studied

chronic obstructive pulmonary disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description

Interleukin-6

Timepoint

beginning and end of supplementation

Method of measurement

ELISA

2

Description

spirometry

Timepoint

beginning and end of supplementation

Method of measurement

Spirometere

3

Description
Anthropometric measurements
Timepoint
beginning and end of supplementation
Method of measurement
Bioelectric impedance device

4

Description
Blood pressure
Timepoint
beginning and end of supplementation
Method of measurement
sphygmomanometer

5

Description
Dietary intake
Timepoint
beginning and end of supplementation
Method of measurement
Food record form

6

Description
Physical activity
Timepoint
beginning and end of supplementation
Method of measurement
international physical activity questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: nano-curcumin supplement, one capsule daily, each capsule contains 80 mg of curcumin in the form of nanomicelles, for 12 weeks, consumed with food, produced by Sina company.
Category
Treatment - Drugs

2

Description
Control group: Placebo, one capsule daily, each capsule consists of polysorbate, propylene glycol and distilled water for 12 weeks, consumed with food, produced by Sina company.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini hospital
Full name of responsible person
Rasoul Zarrin
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice chancellor for research, Urmia 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
Oroumia University of Medical Sciences
Full name of responsible person
Rasoul Zarrin
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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