

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Investigating the effect of nano-curcumin supplementation on ventilatory capacity, pulmonary 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

Country

Iran (Islamic Republic of)

Phone

+98 44 3278 0803

Email address

mahdieh.zareie72@gmail.com

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

Street address

Emam Khomeini Hospital, Ershad Blvd., Ayatollah Modares Blvd

City

Urmia

Province

West Azarbaijan

Postal code

81351-57157

Phone

+98 44 3345 9538

Email

wwzarrin@hotmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Rasoul Zarrin

Street address

Emam Khomeini hospital., Ershad Blvd., Ayatollah Modares Blvd

City

Urmia

Province

West Azarbaijan

Postal code

81351-57157

Phone

+98 44 3345 9538

Email

wwzarrin@hotmail.com

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

Fax**Email**

mahdieh.zareie72@gmail.com

Person responsible for general inquiries**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Rasoul Zarrin

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Orjhans Street, Resalat Blvd

City

Urmia

Province

West Azarbaijan

Postal code

571478334

Phone

+98 44 3222 9059

Email

mahdieh.zareie72@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Mahdieh Zareie

Position

Student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Nutrition department, school of medical sciences,
Urmia University of Medical Sciences, Nazlou Rd.

City

Urmia

Province

West Azarbaijan

Postal code

571478334

Phone

+98 44 3278 0803

Person responsible for updating data**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Mahdieh Zareie

Position

Student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Nutrition department, school of medical sciences,
Urmia University of Medical Sciences, Nazlou Rd.

City

Urmia

Province

West Azarbaijan

Postal code

571478334

Phone

+98 44 3278 0803

Fax**Email**

mahdieh.zareie72@gmail.com

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