Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of gene expression, methylation and secretory level of cytokines and inflammatory chemokines in COPD patients receiving nanocurcumin supplementation compared with patients receiving placebo

Protocol summary

Study aim

Evaluation of gene expression, methylation and secretory level of cytokines and inflammatory chemokines in COPD patients receiving nanocurcumin supplementation compared with patients receiving placebo

Design

30 patients with COPD receiving 80 mg of nanocurcumin daily for 90 days and 30 patients receiving placebo before and after the intervention will receive 10 cc of blood containing anticoagulant to isolate PBMC.

Settings and conduct

This project will be carried out in Tabriz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosed with COPD with stage B, C, or D according to GOLD 2019. Age between 40-75 years old. Both genders. Smoker or less than 6 months of smoking cessation time. Exclusion Criteria: Asthma and other pulmonary-related diseases and injuries (including lung tuberculosis, restrictive lung disease, idiopathic pulmonary fibrosis, or lung cancer). Acute and/or active infection. Cancer. Patients with complex cardiovascular diseases (including valvular heart disease, cardiomyopathy, arrhythmia, congenital heart disease, hypertrophy syndrome). Liver and kidney failure. Pregnancy. Patients with life expectancy less than 6 months due to concomitant illness. Under immunosuppressive treatment within 8 weeks of the first screening visit.

Intervention groups

30 patients with COPD receiving 80 mg of nanocurcumin daily for 90 days and 30 patients receiving placebo before and after the intervention will receive 10 cc of blood containing anticoagulant to isolate PBMC.

Main outcome variables

gene expression, methylation and secretion levels of cytokines IL-1, IL-6, IL-18, IFN-γ and TNF-α and Chemokines CXCL8 and CCL2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200324046851N2**
Registration date: **2022-02-22, 1400/12/03**
Registration timing: **prospective**

Last update: **2022-02-22, 1400/12/03**
Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Majid Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 4665

Email address

ahmadi.m@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2022-06-04, 1401/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of gene expression, methylation and secretory level of cytokines and inflammatory chemokines in COPD patients receiving nanocurcumin supplementation compared with patients receiving placebo

Public title

Evaluation of gene expression, methylation and secretory level of cytokines and inflammatory chemokines in COPD patients receiving nanocurcumin supplementation compared with patients receiving placebo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed with COPD with stage B, C, or D according to GOLD 2019.. Age between 40-75 years old. Both genders. Smoker or less than 6 months of smoking cessation time

Exclusion criteria:

Asthma and other pulmonary-related diseases and injuries (including lung tuberculosis, restrictive lung disease, idiopathic pulmonary fibrosis, or lung cancer). Acute and/or active infection. Cancer. Patients with complex cardiovascular diseases (including valvular heart disease, cardiomyopathy, arrhythmia, congenital heart disease, hypertrophy syndrome). Liver and kidney failure. Pregnancy. Patients with life expectancy less than 6 months due to concomitant illness. Under immunosuppressive treatment within 8 weeks of the first screening visit

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and the lead researcher were unaware of medication or placebo in different patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Academic Committee on Research Ethics (Studies in Human Subjects) tabriz University of Medical Scien

Street address

Golgasht St., Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2021-11-14, 1400/08/23

Ethics committee reference number

IR.TBZMED.REC.1400.767

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease (COPD)

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes

1

Description

IL-1

Timepoint

Day 0 and day 90 after receiving the drug

Method of measurement

ELISA and PCR

2

Description

CCL2

Timepoint

Day 0 and day 90 after receiving the drug

Method of measurement

ELISA and PCR

3

Description

CXCL8

Timepoint

Day 0 and day 90 after receiving the drug

Method of measurement
ELISA and PCR

4

Description
IL-6
Timepoint
Day 0 and day 90 after receiving the drug
Method of measurement
ELISA and PCR

5

Description
IL-18
Timepoint
Day 0 and day 90 after receiving the drug
Method of measurement
ELISA and PCR

6

Description
IFN-γ
Timepoint
Day 0 and day 90 after receiving the drug
Method of measurement
ELISA and PCR

7

Description
TNF-α
Timepoint
Day 0 and day 90 after receiving the drug
Method of measurement
ELISA and PCR

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Nanocurcumin recipient.From 30 patients with COPD receiving 80 mg of nanocurcumin daily for 90 days before and after the intervention, 10 cc of blood containing anticoagulant will be taken to isolate PBMC
Category
Treatment - Drugs

2

Description
Control group: Placebo receiving group. From 30 patients with COPD receiving pelacebo daily for 90 days before and after the intervention, 10 cc of blood containing anticoagulant will be taken to isolate PBMC
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital, Tabriz University of Medical Sciences
Full name of responsible person
Ali Hazrati
Street address
Golgasht St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3335 2073
Email
imamreza@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ziba Mujtahid
Street address
Golgasht
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3335 5921
Email
hrmnet@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Ali Hazrati
Position
Student
Latest degree
Master
Other areas of specialty/work
Immunology
Street address
Marzdaran
City
Tabriz
Province
East Azarbaijan
Postal code
5158963161
Phone
+98 41 3638 7391
Email
alihazrati833@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ali Hazrati
Position
Student
Latest degree
Master
Other areas of specialty/work
Immunology
Street address
Golgasht
City
Tabriz
Province
East Azarbaijan
Postal code
5158963161
Phone
+98 41 3638 7391
Email
alihazrati833@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ali Hazrati
Position
Student
Latest degree
Master
Other areas of specialty/work
Immunology
Street address
Golgasht
City
Tabriz
Province
East Azarbaijan
Postal code
5158963161
Phone
+98 41 3638 7391
Email
alihazrati833@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
Not applicable
Data Dictionary
Not applicable