

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effects of nano curcumin supplementation on the reduction of inflammation and mortality in patients with coronavirus 2019 admitted to ICU ward of Imam Reza hospital in Tabriz

Protocol summary

Study aim

Effects of nano curcumin supplementation on the reduction of inflammation and mortality in patients with coronavirus 2019 admitted to ICU ward of Tabriz Imam Reza Hospital

Design

A randomized, controlled, double-blind, placebo-controlled clinical trial

Settings and conduct

Imam Reza Hospital, This study is a double-blind randomized clinical trial on two statistical populations, including patients with coronavirus in the ICU who receive four drugs oseltamivir, hydroxychloroquine, lopinavir, and ribavirin. Now, patients with the above conditions are divided into two groups receiving 240 mg daily oral nano curcumin and placebo recipients, both of which will have a treatment duration of 14 days. After sampling from both groups and isolating mononuclear cells (PBMC) from them, the expression levels of IL-1, IL-6, IL-17, and TNF- α genes were quantified using the Quantitative Real-Time PCR method. And after the intervention, it will be measured. On the other hand, the ELISA technique is used to evaluate the levels of IL-1, IL-6, IL-17 and TNF- α secreting cytokines.

Participants/Inclusion and exclusion criteria

- In accordance with clinical diagnosis or etiologic criteria for coronavirus pneumonia (COVID-19).
- Willingness to cooperate
- Age range from 18 to 8 years
- Not logged in:
- Nutrition and antioxidant supplements and alpha-lipoic acid during one month before the study
- Pregnancy and lactation
- Severe immune suppression (HIV infection, long-term use of immunosuppressive agents)

Intervention groups

The intervention group will receive 240 mg nano curcumin and the control group will receive placebo capsules daily. Patients will be given daily capsules in

packs containing 60 capsules and we ask patients to take three capsules daily for 14 days.

Main outcome variables

Gene expression rate; cytokine secretion rate; clinical observations; laboratory observations

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200324046851N1**
Registration date: **2020-04-03, 1399/01/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-03, 1399/01/15**

Update count: **0**

Registration date

2020-04-03, 1399/01/15

Registrant information

Name

Majid Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 4665

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-29, 1399/01/10

Expected recruitment end date

2020-04-29, 1399/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of nano curcumin supplementation on the reduction of inflammation and mortality in patients with coronavirus 2019 admitted to ICU ward of Imam Reza hospital in Tabriz

Public title

Effects of nano curcumin supplementation on the reduction of inflammation and mortality in patients with coronavirus 2019 admitted to ICU ward of imam Reza hospital in Tabriz

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Confirmation of positive for coronavirus by RT-pcr
Willingness to cooperate In accordance with clinical diagnosis or etiologic criteria for coronavirus pneumonia (COVID-19). Able to sign informed consent

Exclusion criteria:

Nutrition and antioxidant supplements and alpha lipoic acid during one month before study
Pregnancy and lactation
Severe immune suppression (HIV infection, long-term use of immunosuppressive agents)
Unwillingness to continue cooperation

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Researchers, nurses, and patients have no knowledge of medication or placebo because they are distributed equally among patients and control group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

Univesity Main St,Tabriz,East Azerbaijan Province

City

Tabriz

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East Azarbaijan

Postal code

5166614766

Approval date

2020-03-18, 1398/12/28

Ethics committee reference number

IR.TBZMED.REC.1398.1314

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

COVID-2019

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

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

Expression of peripheral blood mononuclear cell (PBMC)- Genes Expressed in Nano-Curcumin Patients with Control Group (Before and After Treatment)

Timepoint

At baseline and 14 days later

Method of measurement

Real time Polymerase chain reaction

2**Description**

The secretion rate of peripheral blood mononuclear cell (PBMC)-treated cytokines in nano-curcumin patients and control group (before and after treatment)

Timepoint

At baseline and 14 days later

Method of measurement

Elisa kit

3

Description

Clinical features

Timepoint

At baseline and 14 days later

Method of measurement

Clinical observations by specialists

4

Description

Laboratory observations

Timepoint

At baseline and 14 days later

Method of measurement

Review by a pulmonary specialist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Nanocurcumin, which is curcumin, is derived from the yellow-cucumber plant, which is embedded in nano-lipid structures for further absorption. The drug is manufactured by Exir Sina. The intervention group will receive 240 mg of nano curcumin in 3 capsules of 80 mg daily.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive 3 placebo capsules daily, which is similar to the nano curcumin capsule daily.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital in Tabriz

Full name of responsible person

Hamed Valizadeh

Street address

Golestan st, Tabriz, East Azerbaijan Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hassan soleimanpor

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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

Majid Ahmadi

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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

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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