

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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- $\alpha$  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- $\alpha$  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

##### Email address

ahmadi.m@tbzmed.ac.ir

##### 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

**Province**

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

##### **City**

Tabriz

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5166/15731

##### **Phone**

+98 41 3334 7056

##### **Email**

iro@tbzmed.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Hassan soleimanpor

##### **Street address**

Golgasht Street, Tabriz, East Azerbaijan Province

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iro@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**

Majid Ahmadi

##### **Position**

Consultant

##### **Latest degree**

Ph.D.

##### **Other areas of specialty/work**

Immunology

##### **Street address**

Department of Immunology-Faculty of Medicine-  
University Ave- Tabriz-Iran

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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**

Assistant professor

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Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact****Name of organization / entity**

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**Full name of responsible person**

Ramin Pourakbari

**Position**

Consultant

**Latest degree**

Bachelor

**Other areas of specialty/work**

Immunology

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Ramin.prb@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