

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of the Effect of Turmeric Extract and Placebo Capsule on Alpha Tumor Necrosis Factor (TNF- $\alpha$ ) Inflammatory Factor Interleukin-6 (IL-6) and Inflammatory Factor 1-Beta (IL-1 $\beta$ ) in Patients with Covid-19

#### Protocol summary

##### Study aim

Determining the effect of turmeric extract on clinical and laboratory symptoms of patients with Covid-19

##### Design

This study was designed as a double-blind randomized controlled clinical trial (RCT) with placebo.

##### Settings and conduct

120 samples are selected use blood sampling referred to the affiliated hospitals of Shahid Beheshti University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria :Includes people with laboratory confirmation of Covid virus 19 Age over 15 years  
Exclusion criteria Patient request to leave the study for any reason Request the treating physician to exclude the patient from the study for any reason History of drug allergies Patients with hypertension Group of patients with underlying disease

##### Intervention groups

Alcoholic extract of turmeric will be purchased from Zarband Company and will be received in sterile packages. Prior to purchase, the manufacturer will receive a Certificate of Sale and Good Manufacturing Practice. The sample received from this company will be sent to Zarband Pharmaceutical Company before the final order for analysis of curcuminoids, content and microbial test, and the result of the analysis will be received. The microcrystalline cellulose compound under the brand name AVICEL will be purchased as a placebo from the pharmaceutical company (Exir, Iran). The powder obtained in the pharmaceutical factory (Osweh, Iran) will be packaged in an orange gelatin capsule (400 mg) and in a brown opaque can. Placebo is also available in capsules of the same color and size as the drug in similar cans.

##### Main outcome variables

Interleukin-six (IL-6), interleukin-one beta (IL-1 $\beta$ ), tumor

necrosis factor-alpha (TNF- $\alpha$ ), fibrinogen, d-dimer, ferritin, International Normalized Ratio (INR), reaction protein C(CRP)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201111049348N2**

Registration date: **2021-02-25, 1399/12/07**

Registration timing: **prospective**

Last update: **2021-02-25, 1399/12/07**

Update count: **0**

##### Registration date

2021-02-25, 1399/12/07

##### Registrant information

##### Name

Shokoofe Noori

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2387 2570

##### Email address

shnoori@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-28, 1399/12/10

##### Expected recruitment end date

2021-03-15, 1399/12/25

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the Effect of Turmeric Extract and Placebo Capsule on Alpha Tumor Necrosis Factor (TNF- $\alpha$ ) Inflammatory Factor Interleukin-6 (IL-6) and Inflammatory Factor 1-Beta (IL-1 $\beta$ ) in Patients with Covid-19

**Public title**

The Effect of Turmeric Extract on the Treatment of Patients with Covid-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Includes people with laboratory confirmation of Quid 19 virus regardless of clinical signs and close association  
Age over 15 years

**Exclusion criteria:**

History of drug allergies  
History of allergies  
Patients with immunodeficiency  
Patients with hypertension  
Group of patients with underlying disease

**Age**

From **15 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **120**

More than 1 sample in each individual

Number of samples in each individual: **2**

Blood samples are taken on the first day before the intervention and on the tenth day after the intervention for the main and routine variables of the study.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this research, the law of random allocation has been used. Thus, in the above study, with a sample size of 120 people, 60 balls for the intervention group (consumers of capsules turmeric extract ) with the title A and 60 balls for the control group (users of placebo capsules) with the title B were placed in a lottery container. And then randomly for each patient the balls are taken out of the container without replacement and the sequence created for each patient is recorded.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Because the capsule containing turmeric extract and the placebo are exactly the same color and size, patients

and the research team are unaware of its contents, and only the treating physician knows which patient has taken which capsule.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Shahid Beheshti University of Medical Sciences

**Street address**

Velenjak Daneshjo Boulevard Kodakyar Alley

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2021-01-29, 1399/11/10

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1399.581

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

People with COVID 19 whose disease has been confirmed by Real Time PCR.

**ICD-10 code**

U07.1

**ICD-10 code description**

Virus identified

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

Interleukin 6( IL-6)

**Timepoint**

Measurements of variable are performed on the first day before the intervention and on the 10th day after the intervention

**Method of measurement**

Using the kit

**2****Description**

Interleukin One Beta( IL-1 $\beta$ )

### **Timepoint**

Measurements of variable are performed on the first day before the intervention and on the 10th day after the intervention

### **Method of measurement**

Using the kit

### **3**

#### **Description**

Alpha tumor necrosis factor(TNF- $\alpha$ )

#### **Timepoint**

Measurements of variable are performed on the first day before the intervention and on the 10th day after the intervention

#### **Method of measurement**

Using the kit

## **Secondary outcomes**

### **1**

#### **Description**

The international normalized ratio (INR)

#### **Timepoint**

Sampling is done on the first day before the intervention and on the 10th day after the intervention for the main and routine variables of the study

#### **Method of measurement**

Through a clinical laboratory

### **2**

#### **Description**

D -Dimmer

#### **Timepoint**

Sampling is done on the first day before the intervention and on the 10th day after the intervention for the main and routine variables of the study.

#### **Method of measurement**

Through a clinical laboratory

### **3**

#### **Description**

Fibrinogen

#### **Timepoint**

Sampling is done on the first day before the intervention and on the 10th day after the intervention for the main and routine variables of the study.

#### **Method of measurement**

Through a clinical laboratory

### **4**

#### **Description**

Ferritin

#### **Timepoint**

Sampling is done on the first day before the intervention and on the 10th day after the intervention for the main and routine variables of the study.

#### **Method of measurement**

Through a clinical laboratory

### **5**

#### **Description**

C Reactive Protein (CRP)

#### **Timepoint**

Sampling is done on the first day before the intervention and on the 10th day after the intervention for the main and routine variables of the study.

#### **Method of measurement**

Through a clinical laboratory

## **Intervention groups**

### **1**

#### **Description**

Alcoholic extract of turmeric will be purchased from Zarband Company and will be received in sterile packages. Prior to purchase, the manufacturer will receive a Certificate of Sale and Good Manufacturing Practice. The sample received from this company will be sent to Zarband Pharmaceutical Company before the final order for analysis of curcuminoids, content and microbial test, and the result of the analysis will be received. To encapsulate the extract of turmeric in the encapsulating device, about 5% by weight, silica (SiO<sub>2</sub>) will be added to the extract and mixed thoroughly. The powder obtained in the pharmaceutical factory (Osweh, Iran) will be packaged in an orange gelatin capsule (400 mg) and in a brown opaque can.

#### **Category**

Placebo

### **2**

#### **Description**

The microcrystalline cellulose compound with the brand name AVICEL (particle diameter: less than 50 micrometers) will be purchased as a placebo from the pharmaceutical company (Exir, Iran).

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Subsidiary hospitals of Shahid Beheshti University of Medical Sciences

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

Mrs Shokofe Noori

##### **Street address**

Student Boulevard, Arabi Alley

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1985711151

##### **Phone**

+98 21 2243 2560

**Email**

taleghanihospital@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Vice Chancellor for Research, Dr.Afshin Zarghi

**Street address**

Koodkiar Street, Student Boulevard, Velenjak

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Tehran

**Postal code**

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**Phone**

+98 21 23871

**Email**

info@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mrs Shokofe Noori

**Position**

Associate Professor Shahid Beheshti University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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**Email**

shnoori85@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mrs Shokofe Noori

**Position**

Associate Professor Shahid Beheshti University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mrs Shokofe Noori

**Position**

Associate Professor Shahid Beheshti University of Medical Sciences

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Because patient information is private and not available to the public

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Patients' personal data is private and not available to the public, but the data and results of their analysis will be made available to the public.

**When the data will become available and for how long**

Unlimited

**To whom data/document is available**

public

**Under which criteria data/document could be used**

To improve people's knowledge about whether curcumin modulates the clinical symptoms of COVID 19 patients.

**From where data/document is obtainable**

Databases

**What processes are involved for a request to access data/document**

Refer to the database and access to information

**Comments**