Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effect of Turmeric Extract and Placebo Capsule on Alpha Tumor Necrosis Factor (TNF-α) Inflammatory Factor Interleukin-6 (IL-6) and Inflammatory Factor 1-Beta (IL-1β) 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-1β), tumor necrosis factor-alpha (TNF-α), 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@sbmu.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-α) Inflammatory Factor Interleukin-6 (IL-6) and Inflammatory Factor 1-Beta (IL-1β) 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-1β)

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-α)
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 (SiO2) 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
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Tehran
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1985711151
Phone

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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

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Koodkiar Street, Student Boulevard, Velenjak

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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

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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mrs Shokofe Noori

Position

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Latest degree

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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