

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The effect of combined capsule black pepper (sativa linn) black cumin) and Curcuma Longa on inflammation factors and lipid profiles and acute phase proteins in patients with covid-19 hospitalized

#### Protocol summary

##### Study aim

Evaluation the effect of black pepper extract and black seed and turmeric on inflammatory factors and acute phase lipid and protein profiles in patients with Covid - 19 hospitalized

##### Design

A clinical trial with a control group with parallel, double-blind, randomized, phase 3 groups on 60 patients will be randomized using randomized blocking method

##### Settings and conduct

all patients with Covid-19 in the age range of 20 to 70 years who are admitted to the covid-19 ward of Khatam al- Anbia Hospital in Shoushtar will be eligible to enter the study. The number of participants in each group is 30. Full explanations of the study are given and if they agree to enter the study, they will be given written consent. General characteristics questionnaire includes: age, sex, smoking, diet supplements and medications, history of disease and duration of illness and questions about taking antioxidant supplements. A placebo containing wheat flour is prepared in a similar way and in the same shape and color .The patients in the intervention group consume 3 grams of black pepper and turmeric extract daily in hard capsules (1 capsule of 500 mg after lunch and dinner).

##### Participants/Inclusion and exclusion criteria

At first, all patients with Covid-19 in the age range of 20 to 70 years who are admitted to the covid-19 ward of Khatam al-Anbia Hospital in Shoushtar will be eligible for inclusion in the study. Exclusion criteria include supplementation Less than 80% of the total is the change in the type and amount of drug used during the intervention and the unwillingness to continue cooperation in the study.

##### Intervention groups

Two intervention groups with herbal capsules and the control group with placebo

#### Main outcome variables

CBC,blood lipids(HDL, LDL , TG, CHOLESTROLE),BLOOD SUGER, PT, PTT, blood interleukin 6, D- DIMER, ALT, AST,ALP, BILLI TOTAL , DIRECT), hs-CRP,

#### General information

##### Reason for update

##### Acronym

طب سنتی ، درمان، کوید 19

##### IRCT registration information

IRCT registration number: **IRCT20210804052068N1**

Registration date: **2021-11-23, 1400/09/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-23, 1400/09/02**

Update count: **0**

##### Registration date

2021-11-23, 1400/09/02

##### Registrant information

##### Name

Sima Hashemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3622 8926

##### Email address

simahashemi8491@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-22, 1400/09/01

##### Expected recruitment end date

2022-01-21, 1400/11/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of combined capsule black pepper ,sativa linn )black cumin) and Curcuma Longa on inflammation factors and lipid profiles and acute phase proteins in patients with covid-19 hospitalized

**Public title**

the effect of combined herbal capsule on covid-19 disease

**Purpose**

Treatment

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

Patients admitted to covid-19 wards of the hospital positive pcr test Age range 20 to 70 years Willingness to participate in the study

**Exclusion criteria:**

The patient avoids taking the capsule changing the type and amount of medication taken during the intervention Any changes in treatment plan and disease conditions Chronic diseases such as diabetes, hypertension, cancer, obesity (body mass index above 30) History of drug and food allergies Transfer the patient to the intensive care unit عدم تمایل به ادامه همکاری در مطالعه

**Age**

From **20 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **30**

More than 1 sample in each individual

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

5 ml of blood is taken in the first and fifth days of hospitalization. Blood samples are immediately sent to the laboratory of Khatam Al-Anbia Hospital (PBUH), kept at room temperature for 30 to 45 minutes to clot and then centrifuged at 4 ° C for 15 minutes and its serum sample is separated. Serum samples were stored at minus 80 ° C (38) and then the studied markers were measured by spectrophotometry and ELISA.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To control the effect of confounding factors, individuals are matched in two groups in terms of age, sex, and body mass index. Purposeful sampling is performed among patients with 19 patients admitted to Khatam Al-Anbia Hospital in Shoushtar. In this way, in random selection of samples, blocking is used with the help of

computer drive button, And the method of assigning individuals to the two groups studied is a random blocking method with quadruple blocks. The blocks are selected until they reach the desired volume (60 patients) based on a table of random numbers.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

All steps to be double-blind will be performed by a third party after the coding steps, which means that researchers providing care and patients will not have information on the complementary type until the end of the study. In order to further ensure that the selection bias does not occur after random allocation, the allocation conciliation method will be used by using unique two-digit codes for each person.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

-

**Secondary Ids**

empty

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

Ethics Committee of Shushtar University of Medical Sciences

**Street address**

Rajaei St., Alhadi Hospital, Nursing Department Management Office

**City**

shoushtar

**Province**

Khuzestan

**Postal code**

6451684534

**Approval date**

2021-06-15, 1400/03/25

**Ethics committee reference number**

IR.SHOUSHTAR.REC.1400.002

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

Covid-19 disease

**ICD-10 code****ICD-10 code description****Primary outcomes**

## 1

### Description

Age, history of disease, history of use of immunosuppressive drugs, sex, level of education, length of hospital stay, economic status, blood lipids, blood interleukins, hs-CRP

### Timepoint

From the first of November 2021 to the first of July 2022

### Method of measurement

the studied markers are measured by spectrophotometric and ELISA methods.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients consuming herbal capsules of a combination of black pepper, black seed and turmeric

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients taking placebo containing capsules filled with wheat flour

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khatam al-Anbia Hospital in Shushtar

##### Full name of responsible person

sima hashemi

##### Street address

Shahid Rajaei crossroads-Alhadi Hospital, Director of Nursing Department

##### City

shoushtar

##### Province

Khouzestan

##### Postal code

6451684534

##### Phone

+98 61 3622 8926

##### Fax

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##### Email

simahashemi8491@gmail.com

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shooshtar University of Medical Sciences

##### Full name of responsible person

sima hashemi

##### Street address

Shahid Rajaei crossroads

##### City

shoushtar

##### Province

Khouzestan

##### Postal code

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#### Grant name

Shushtar university of Medical Sciences

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shooshtar 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

Shooshtar University of Medical Sciences

##### Full name of responsible person

sima hashemi

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

nursing

##### Street address

Shahid Rajaei Crossroads

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

Shooshtar University of Medical Sciences

**Full name of responsible person**

sima hashemi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**Rajaei street , Alhadi hospital, Nursing Department  
Management Office**City**

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**Province**

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

Shooshtar University of Medical Sciences

**Full name of responsible person**

sima hashemi

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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