Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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
Khouzestan
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 2021to 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

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Sponsors / Funding sources

1

Sponsor

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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

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Person responsible for updating data

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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