Evaluation of the effect of nano micelles containing curcumin (Sina Ccurcumin) as a therapeutic supplement in patients with COVID-19 and investigating of immune responses balance changes following treatment: A randomized double blind clinical trial.

Protocol summary

**Study aim**
Clinical study to investigate the effectiveness of curcumin-containing nanomaterials and its effects on immune cell balance as a therapeutic supplement in the treatment of COVID-19

**Design**
Clinical trial with control groups using placebo with parallel group, double-blind, randomized trials will be performed on 40 COVID-19 patients which will be randomized using encoded sealed wax boxes.

**Settings and conduct**
Patients are selected from the COVID-19 ward of Shahid Mohammadi Hospital in Bandar Abbas. Patients who enter the study receive standard treatment with nanocurcumin or placebo within two weeks. The study is blinded by the therapist, patient, data collector, and analyzer through randomly encoded boxes. On days 1, 7, and 14 of the study, clinical history and blood samples are taken from patients.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Laboratory-approved COVID-19 tests Both gender Age between 18 and 75 years Signing a written consent Lack of participation in other clinical trials Exclusion criteria Pregnancy and lactation Allergy to turmeric or curcumin Smoking Patient connected to the ventilator SaO2 less than 90% or PaO2 less than 8 kPa Having comorbidities (such as severe renal failure Glomerular filtration rate less than 30 ml / min, liver failure Congestive heart failure, or Chronic obstructive pulmonary disease) History of gallstones History of gastritis or active gastrointestinal ulcer

**Intervention groups**
In addition to the usual treatments, in the intervention group, 40mg nanocurcumin capsules 4 mg per day (after breakfast, lunch and dinner, one before bedtime) for 2 weeks, and in the placebo group, capsules with the same appearance are prescribed

**Main outcome variables**
Effectiveness of nano micelles containing curcumin as a complementary treatment in improving symptoms of patients with COVID-19 and examining changes in the immune cell balance

**General information**

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: IRCT20200611047735N1
Registration date: 2020-06-19, 1399/03/30
Registration timing: prospective

Last update: 2020-06-19, 1399/03/30
Update count: 0

**Registration date**
2020-06-19, 1399/03/30

**Registrant information**
Name
Amin Reza Nikpoor

**Name of organization / entity**
Country
Iran (Islamic Republic of)

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**Email address**
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**Recruitment status**
recruiting

**Funding source**

**Expected recruitment start date**
Evaluation of the effect of nano micelles containing curcumin (Sina Ccurcumin) as a therapeutic supplement in patients with COVID-19 and investigating of immune responses balance changes following treatment: A randomized double blind clinical trial.

Public title
Evaluation of the effect of nano micelles containing curcumin (Sina Ccurcumin) as a therapeutic supplement in patients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
- Laboratory-approved COVID-19 tests (2019-nCoV Real-Time RT-PCR) (preferably at a particular center or university-approved center) regardless of clinical manifestations and close contact history
- Signing a written consent form
- No simultaneous participation in other clinical trials

Exclusion criteria:
- Pregnancy and lactation
- History of allergy to turmeric or curcumin products
- Smoking (more than 5 cigarettes a day)
- Patient connected to the ventilator
- Clinical evidence for respiratory failure at the time of hospitalization / admission (SaO2 ≤ 90% or PaO2 <8 kPa)
- Having comorbidities (such as severe renal failure, Glomerular filtration rate less than 30 ml / min, liver failure, Congestive heart failure, or Chronic obstructive pulmonary disease)
- History of gallstones
- History of gastritis or active gastrointestinal ulcer

Age
- From 18 years old to 75 years old

Gender
- Both

Phase
- N/A

Groups that have been masked
- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
- Target sample size: 40

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method in this study is used as an individual randomization using a sealed sealed envelope randomization tool. In this case, the third person was responsible for picking up and selecting the envelopes as a random arrangement in which the placebo and the main drug were randomly divided among the patients. The study person and the analyst will not be aware of how the randomization happened.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to perform the blinding, according to the number of patients, the nanocurcumin and placebo, which are quite similar in shape and characteristics, is randomly placed in the same boxes and the boxes are coded. The codes related to the drug and placebo will be provided by a third party, and the therapist, patient, data collector, and analyzer will not be notified, and the boxes will be given to patients upon arrival.

Placebo
- Used

Assignment
- Parallel

Other design features

Secondary Ids
- empty

Ethics committees

1

Ethics committee
Name of ethics committee
- Ethics committee of Hormozgan University of Medical Sciences

Street address
- Imam Hussain Blvd, School of Medicine, Immunology Department

City
- Bandar Abbas

Province
- Hormozgan

Postal code
- 7916613885

Approval date
- 2020-06-10, 1399/03/21

Ethics committee reference number
- IR.HUMS.REC.1399.174

Health conditions studied

1

Description of health condition studied
- COVID-19

ICD-10 code
- U07.1

ICD-10 code description
- COVID-19, virus identified
Primary outcomes

1 Description
Clinical symptoms

Timepoint
On a weekly basis, patients are examined clinically on days 1, 7, and 14

Method of measurement
Clinical examinations

2 Description
Immune cell balance

Timepoint
On a weekly basis, blood samples are taken from patients and patients are examined on days 1, 7 and 14.

Method of measurement
Molecular experiments

Secondary outcomes

empty

Intervention groups

1 Description
Intervention group: Patients with COVID-19, in addition to routine drug treatment, will receive 40 mg of nano curcumin capsules 4 times a day (one for breakfast, one for lunch, one for dinner and one before bedtime) for 2 weeks.

Category
Treatment - Drugs

2 Description
Control group: COVID-19 patients will receive 4 placebo a day (after breakfast, lunch and dinner one and one before bedtime) for 2 weeks in addition to routine medication.

Category
Treatment - Drugs

Recruitment centers

1 Recruitment center
Name of recruitment center
Shahid Mohammadi hospital

Full name of responsible person
Amin Reza Nikpoo

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Sponsors / Funding sources

1 Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences

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Grant name
990126

Grant code / Reference number

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

Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences

Full name of responsible person
Amin Reza Nikpoo

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work

Immunology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
After extraction, the data will be analyzed for presentation as a scientific paper and report.

When the data will become available and for how long
After the study, it is possible to access

To whom data/document is available
There are no restrictions on access.

Under which criteria data/document could be used
The rights to use the project are reserved. If there is a request to access the data, it will be done with the opinion of the correspondence of the present project and the type of use of the data will be according to the opinion of the correspondence of the present project.

From where data/document is obtainable
Correspondence with correspondence of the present project.

What processes are involved for a request to access data/document
In order to access the data, it will be decided by correspondence of the present project.

Comments