Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2020

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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+98 76 3333 7192

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nikpoora@hums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2020-07-05, 1399/04/15

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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 Nikpoor
Street address
Jomhouri eslami Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
teymour agha mollaie
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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

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Person responsible for updating data

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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