

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

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)

Phone

+98 76 3333 7192

Email address

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 ($SaO_2 \leq 90\%$ or $PaO_2 < 8$ 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

Jomhuri eslami Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Phone

+98 76 3333 7192

Email

nikpoora@hums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

teymour agha mollaie

Street address

Jomhuri esmami Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Phone

+98 76 3333 7192

Email

nikpoora@hums.ac.ir

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
Street address
Immunology Department, School of Medicine, Imam-
Hussein Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919693116
Phone
+98 76 3371 0370
Email
nikpoora@hums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Amin Reza Nikpoor
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
Immunology Department, School of Medicine, Imam-
Hussein Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919693116
Phone
+98 76 3371 0370
Email
nikpoora@hums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Amin Reza Nikpoor
Position
Assistant professor
Latest degree
Ph.D.

Other areas of specialty/work

Immunology
Street address
Immunology Department, School of Medicine, Imam-
Hussein Blvd
City
Bandar Abbas
Province
Hormozgan
Postal code
7919693116
Phone
+98 76 3371 0370
Email
nikpoora@hums.ac.ir

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