Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the effect of curcumex supplement on the symptoms of patients with COVID-19

Protocol summary

Study aim
The effectiveness of Corcomex in reducing the symptoms of Covid-19
Design
This clinical trial has a control group, double-blind, randomized, in phase 2 and on 100 people. The method of randomization was simple randomization.
Settings and conduct
The study was conducted in the city of Sari. The study was double-blind, where the researcher, participants and data analysts were blind.
Participants/Inclusion and exclusion criteria
Inclusion criteria: patients who had a ground glass opacity in the lung CT scan, Clinical symptoms of COVID19, having a history of contact with a corona patient, recent travel to high-risk areas, People who had a positive PCR result. Exclusion criteria: patients who were not able to take the medicine orally and the patient's lack of satisfaction in participating in the study.
Intervention groups
Both groups will receive routine medications prescribed for outpatients. In addition to these treatments, one group will receive Curcomex capsules daily, and the control group will receive a placebo.
Main outcome variables
Recovery time

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230125057216N1**
Registration date: **2023-09-26, 1402/07/04**
Registration timing: **retrospective**

Last update: **2023-09-26, 1402/07/04**
Update count: **0**

Registration date
2023-09-26, 1402/07/04

Registrant information
Name
Gholamreza Houshmand
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 11 3456 1759
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-03-21, 1402/01/01
Expected recruitment end date
2023-05-22, 1402/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of curcumex supplement on the symptoms of patients with COVID-19

Public title
Evaluating the effect of curcumex supplement on the symptoms of patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ground glass opacity in lung CT scan Clinical symptoms such as dry cough- dyspnea-fever- weakness- diarrhea-

headache-rhinorrhea- or history of contact with COVID19 patient or recent travel to high-risk areas Positive Covid-19PCR

Exclusion criteria:

PO intolerance Dissatisfaction for Participation in research

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization was simple randomization, which was done using a table of random numbers. After determining the framework of the statistical population, among the 60 participants identified by numbers 1-60, 30 numbers are randomly extracted using the random number table, and these 30 participants are placed in the intervention group in the order of entry into the study as For example, if the numbers 3, 4, and 10 are obtained from the table of random numbers, it means that the third, fourth, and tenth patients included in the study will be in the intervention group, then the intervention group was given medicine and the control group was given placebo, which is both placebo and Both drugs were in completely similar packages.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study was conducted in double blinded, in which the main researcher, health personnel involved in the study, participants and data analyzer were blind. The participants were divided into intervention and control groups, in addition to normal treatment, intervention group take medication and control group take placebo. medication and the placebo were in the form of capsules with the same color, shape and size and were distinguished only by inserting a batch number.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences and Health Services Building No. 2, Moalem Square, Sari

City

Sari

Province

Mazandaran

Postal code

0000000000

Approval date

2021-12-07, 1400/09/16

Ethics committee reference number

IR.MAZUMS.REC.1400.593

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

Investigation of the improvement rate of clinical symptoms of patients including cough, dyspnea, weakness, fever and diarrhea one month after take medication.

Timepoint

At the beginning of the study and one month later

Method of measurement

history and physical examination

Secondary outcomes

1

Description

White blood cell counts

Timepoint

At the beginning of the study and after 30 days from the start of taking medication

Method of measurement

lab data

2

Description
ESR
Timepoint
At the beginning of the study and after 30 days from the start of taking medication
Method of measurement
lab data

3

Description
CRP
Timepoint
At the beginning of the study and after 30 days from the start of taking medication
Method of measurement
lab data

4

Description
Comparison of the effect of Curcumex treatment on changes in serum creatinine
Timepoint
At the beginning of the study and after 30 days from the start of taking medication
Method of measurement
lab data

5

Description
Comparison of the effect of Curcumex treatment on changes in liver enzymes
Timepoint
At the beginning of the study and after 30 days from the start of taking medication
Method of measurement
lab data

Intervention groups

1

Description
Intervention group: In the intervention group, 30 patients were treated with Curcumex, which is a combination of three ingredients (320 mg of turmeric, 150 mg of ginger, and 4 mg of black pepper) in capsule form. This drug was developed by the Department of Pharmacology of Jundishapur University of Ahvaz. this medication use twice daily, which lasts up to 30 days. During the treatment period, patients will have three visits for training and control of clinical symptoms and laboratory findings.
Category
Treatment - Drugs

2

Description
Control group: In the control group, 30 patients were treated with placebo, which was similar in appearance to the original drug. This drug was developed by the Department of Pharmacology of Jundishapur University of Ahvaz. this medication use twice daily, which lasts up to 30 days. During the treatment period, patients will have three visits for training and control of clinical symptoms and laboratory findings.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam hospital in Sari
Full name of responsible person
Gholamreza Houshmand
Street address
Razi Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
Proportion provided by this source

35

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
Mazandaran University of Medical Sciences

Full name of responsible person
Gholamreza Houshmand

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

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Email
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
After the end of the study, according to the rules of the Ethics Committee of the Ministry of Health, the non-identifiable data of the participants in the study will be published in a limited manner in the dissertation and article.

When the data will become available and for how long
The data access period starts one month after the publication of the study results.

To whom data/document is available
The data of this study will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The documentation of this study will be made available to other researchers for the purpose of conducting further research and for the purpose of using them in the production or development of drugs effective against the Covid-19.

From where data/document is obtainable

The office of Dr. Gholamreza Houshmand is located at km 18 of Farah Abad Road, Department of Pharmacology, Faculty of Medicine.

Email:Dr.houshmand_pharma@yahoo.com

What processes are involved for a request to access data/document

After receiving the request via email stating the need to receive data, this request will be reviewed by the main researcher and after the request is approved, the data will be sent.

Comments