

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of anti-inflammatory effect of ZAX.1399.C03 on airways inflammation in patients with coronavirus in home care

Protocol summary

Study aim

Determining the effect of ZAX.1399.C03 on the course of the disease, symptomatic treatment and reduction of inflammatory mediators in COVID-19 patients in home care

Design

The triple blind clinical trial, two treatment groups and parallel control, The stage will be over 60 patients. For randomization, we will use the method of permutation blocks with a number of 6 blocks using Random allocation software.

Settings and conduct

Patients with COVID19 in home care are divided into groups A and B. The anti-inflammatory effects of ZAX.1399.C03 evaluated. The study will be blinded at the level of outcome assessor and statistical analyst of results. Location: Fasa University of Medical Sciences

Participants/Inclusion and exclusion criteria

Admission requirements: 1. Definitive diagnosis of COVID-19 2. Age over 18 years 3. Both sexes (male and female) 4. Having informed and written consent to participate in the study 5. No history of any allergies 6. Do not take anticoagulants 7. Not getting pregnant and breastfeeding 8. No diabetes in the person Conditions for not entering the study: 1. Disagreement of the physician in charge of the patient 2. History of any allergies 3. History of heart and kidney disease 4. Patient disagreement 5. History of high blood pressure

Intervention groups

Divide patients into two similar groups A and B. The treatment group contains capsules containing ZAX.1399.C03 and the placebo group contains capsules containing fried corn flour. By introducing the plan and justifying the patient, written consent is received.

Main outcome variables

1. Serum levels of inflammatory mediators IL6 2. Degree of hemoglobin saturation (SPO2) in the normal range

General information

Reason for update

1. In order to protect the intellectual property of the project, the name of the studied plant product has been removed and the phrase ZAX.1399.C03 has been replaced. 2. The English translation sections have been revised from a grammatical point of view and "minor" changes have been made. 3. The main outcome variable is described in the abstract of serum IL6 level and the degree of hemoglobin saturation of the blood.

Acronym

SICF (مطالعه التهاب و کرونا ویروس فسا)

IRCT registration information

IRCT registration number: **IRCT20210218050404N1**

Registration date: **2021-03-10, 1399/12/20**

Registration timing: **prospective**

Last update: **2021-09-30, 1400/07/08**

Update count: **1**

Registration date

2021-03-10, 1399/12/20

Registrant information

Name

Amin Dakhili Ardestani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 5335 9507

Email address

a.dakhili@fums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of anti-inflammatory effect of ZAX.1399.C03 on airways inflammation in patients with coronavirus in home care

Public title
Control of inflammatory process in patients with coronavirus affected by ZAX.1399.C03

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 COVID-19 is detected by PCR laboratory diagnostic kit
 Age over 18 years Both sexes (male and female) Having informed and written consent to participate in the study
 No history of any allergies No uncontrolled hypertension
 Do not take anticoagulants (aspirin, Plavix, warfarin) Not pregnant and breastfeeding No diabetes in the person
Exclusion criteria:
 Disagreement of the responsible physician of the patient before randomization History of any allergies to drugs, various substances, food and ... History of liver and kidney disease Patient disagreement Inability of the patient to take the drug for any reason History of hypertension and heart disease

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
This study is performed on patients referred to health centers and infectious disease specialists in the present study. For home care patients, the admit code along with the relevant information (medication regimen, age and sex, severity of the disease and severity of symptoms) is provided by the expert to the patient. The relevant expert divides the patients into two similar groups based on the treatment regimen, age group, sex, severity of the disease and symptoms, and randomly divides one group into group A and one group into group B using the patient code numbers. For randomization, the

permutation block method with the number of blocks of 6 is done using Random allocation software.

Blinding (investigator's opinion)
Triple blinded

Blinding description
For blinding, the study of the drug and placebo with the names A and B in the same package are prescribed by the doctor to the patient. (Capsules according to The principles of pharmacy are created by a pharmacist.) A patient-level study, outcome evaluator, and statistical analyst of the results will be blind. Only the manufacturer of the drug can decode the contents of each capsule based on the original retained form of the randomization results The person in charge of drug delivery and the patient, the doctor, the person in charge of evaluating the consequences will not be aware of the coding. The results of the two groups under the headings of groups A and B will be delivered to the statistical analyzer.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Fasa University of Medical Sciences
Street address
 Fasa city, Ibn Sina square
City
 Fasa
Province
 Fars
Postal code
 7461686688

Approval date
2021-02-06, 1399/11/18

Ethics committee reference number
IR.FUMS.REC.1399.156

Health conditions studied

1

Description of health condition studied
Incidence of inflammation due to the mechanism of COVID19

ICD-10 code
U07.1

ICD-10 code description
COVID-19

Primary outcomes

1

Description

Inflammatory mediators of IL6

Timepoint

Before the intervention and seven days after the start of consumption of mango leaf extract

Method of measurement

ELISA test

2

Description

Dry cough

Timepoint

Daily

Method of measurement

Check list

3

Description

Sputum cough

Timepoint

Daily

Method of measurement

Check list

4

Description

Shortness of breath

Timepoint

Daily

Method of measurement

Check list

5

Description

Gastrointestinal manifestations

Timepoint

Daily

Method of measurement

Check list

6

Description

Fever

Timepoint

Daily

Method of measurement

Check list

7

Description

Muscle and joint pain

Timepoint

Daily

Method of measurement

Check list

8

Description

Fatigue and laziness

Timepoint

Daily

Method of measurement

Check list

9

Description

Shiver

Timepoint

Daily

Method of measurement

Check list

10

Description

Odor and taste activity

Timepoint

Daily

Method of measurement

Check list

Secondary outcomes

1

Description

hospitalization in medical centers with normal activity

Timepoint

daily

Method of measurement

Check list

Intervention groups

1

Description

Intervention group: The medicinal composition of ZAX.1399.C03 in two daily doses, is consumed for 7 to 14 days.

Category

Treatment - Drugs

2

Description

Control group: The composition of popcorn flour is consumed, in two daily doses, for a period of 7 to 14 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Hospital, Fasa city

Full name of responsible person

Dr. Seyyed Amin Kouhpayeh

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Ibn Sina square, Fasa city,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa 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

Fasa 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**

Fasa University of Medical Sciences

Full name of responsible person

Amin Dakhili Ardestani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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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

Some of the information obtained will be available based on changes in initial outcomes.

When the data will become available and for how long

Start of access period 6 months after production and publication of results

To whom data/document is available

People engaged in research in medical universities of the country

Under which criteria data/document could be used

The methods and data contained in this clinical trial should be used solely to advance similar projects. It is also necessary to mention the research center of this study (Fasa University of Medical Sciences) if information is used

From where data/document is obtainable

Dr. Seyyed Amin Kouhpayeh Email address: kouhpayeha@gmail.com Contact number: 09177087247 Address: Department of Pharmacology, Fasa University of Medical Sciences and Health Services, Fasa, Iran. Email Address: Amindakhiliardestani@yahoo.com Contact number: 09228584505 Address: Fasa University, Fasa University of Medical Sciences and Health Services, Fasa, Iran.

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

1. Contact the scientific or general respondent of the study
2. Sending their official request to the respondent
3. Apply to the University Research Council
4. In case of a positive response from the council, it will be provided to the applicant in accordance with the ethical principles.
5. The total duration of the process from the time of receiving the request is 20 days.

Comments