

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of therapeutic effects of ZAX.1400.C05 on symptomatic treatment and clinical features of patients with coronavirus: a randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of ZAX.1400.C05 on the course of the disease and symptomatic treatment of COVID-19 patients hospitalized

Design

The double-blind clinical trial, two treatment groups and parallel control will be the third phase on 300 patients. For randomization, we will use the permutation block method using Random allocation software.

Settings and conduct

Patients with COVID-19 admitted to Vali-e-Asr Hospital in Fasa are divided into six similar groups of 50 people. The therapeutic effects of ZAX.1400.C05 on clinical and laboratory parameters of patients will be evaluated. The study will be blinded at the level of outcome assessor, physician, patient, and statistical analyst. Location: Fasa University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of COVID-19 disease by laboratory diagnostic kit from patient sputum
2. The degree of hemoglobin saturation (SPO2) of the patient is between 85% and 93% in patients
3. Diagnosis of lung involvement by CT scan in patients
4. The number of breaths per minute between 25 and 30 in patients
Exclusion criteria: 1. History of allergies to plant products
2. Pregnancy and lactation
3. Existence of liver and kidney diseases
4. Inability of the patient to receive oral medication

Intervention groups

Divide the patients into six groups of 50 similar A, B, C, D, E, F. One of the codes will be related to the placebo and the rest will be the drug. Capsule treatment groups containing ZAX.1400.C05 and placebo groups of capsules containing popcorn flour, every 12 hours. By introducing the patient's plan and justification, written consent is received.

Main outcome variables

Duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210218050404N4**

Registration date: **2022-02-24, 1400/12/05**

Registration timing: **prospective**

Last update: **2022-02-24, 1400/12/05**

Update count: **0**

Registration date

2022-02-24, 1400/12/05

Registrant information

Name

Amin Dakhili Ardestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5335 9507

Email address

a.dakhili@fums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effects of ZAX.1400.C05 on symptomatic treatment and clinical features of patients with coronavirus: a randomized controlled clinical trial

Public title

Evaluation of therapeutic effects of ZAX.1400.C05 on patients with coronavirus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Definitive diagnosis of COVID-19 disease by laboratory diagnostic kit from patient sputum Patient hemoglobin saturation (SPO2) between 85% and 93% in patients Detection of lung involvement by CT scan in patients The number of breaths per minute is between 25 and 30 in patients

Exclusion criteria:

History of allergies to herbal products Pregnancy and lactation Existence of liver and kidney diseases Inability of the patient to receive oral medication

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

This study was performed on patients with coronary artery and hospitalized in Vali-e-Asr Hospital in Fasa. Takes place. For hospitalized patients, the hospital code along with the relevant information (medication regimen, age and sex, severity of disease and severity of symptoms) is provided by the expert to the patient. The relevant expert divides the patients into a group of 250 people and a group of 50 people based on the treatment regimen, age group, sex, severity of the disease and symptoms, and randomly using the code numbers A, B, C, D and E will be done. One of the codes will be for the placebo and the rest will be for the drug. For randomization, the permutation block method is done using Random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

For the blinding of the study, the drug (capsule containing ZAX.1400.C05) and placebo (including capsule of roasted corn flour) are named in the same

package and are prescribed to the patient by the doctor. (Capsules are made according to the principles of pharmacy by a pharmacist.) Before prescribing the drug to the patient, the plan is introduced and written consent is received. Study at the patient level, outcome assessor and statistical analyzer of the results will be blinded. 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 know about the codings. The results of the two groups under the headings of groups A, B, C, D and E will be submitted 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

Ibn Sina square, Fasa.

City

Fasa

Province

Fars

Postal code

7461686688

Approval date

2022-01-05, 1400/10/15

Ethics committee reference number

IR.FUMS.REC.1400.120

Health conditions studied**1****Description of health condition studied**

COVID-19 viral disease

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes**1****Description**

Clinical signs

Timepoint

daily

Method of measurement

Evaluation form (questionnaire)

2**Description**

(VAS) Visual Analogue Scale

Timepoint

daily

Method of measurement

check list

3**Description**

ESR (Erythrocyte sedimentation rate)

Timepoint

Zero and fourteen days after the start of the intervention

Method of measurement

Standard sedimentation rate method

4**Description**

C-Reactive Protein – CRP

Timepoint

Zero and fourteen days after the start of the intervention

Method of measurement

Autoanalyzer

5**Description**

Liver enzymes SGOT, ALT, SGPT

Timepoint

Zero and fourteen days after the start of the intervention

Method of measurement

Autoanalyzer

6**Description**

Renal indicators BUN, Creatinine

Timepoint

Zero and fourteen days after the start of the intervention

Method of measurement

Autoanalyzer

Secondary outcomes**1****Description**

Duration of hospitalization

Timepoint

daily

Method of measurement

check list

2**Description**

Mortality

Timepoint

daily

Method of measurement

check list

Intervention groups**1****Description**

Intervention group: Dried powder of ZAX.1400.C05, made in the laboratory of medicinal plants of Fasa University of Medical Sciences, based on plant flavonoids, in the form of capsules, is consumed in four daily doses for 14 days.

Category

Treatment - Drugs

2**Description**

Control group: The composition of popcorn flour, made in the laboratory of medicinal plants of Fasa University of Medical Sciences, in the form of capsules, is consumed in four daily doses for 14 days.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Vali Asr Hospital, Fasa

Full name of responsible person

Sohrab Najafipour

Street address

Ibn Sina square, Fasa

City

Fasa

Province

Fars

Postal code

4737774617

Phone

+98 71 5331 5011

Fax

+98 71 5331 4021

Email

sohrabnajafipour@yahoo.com

Web page address

<http://vh.fums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Yaser Mansouri

Street address

Ibn Sina square, Fasa

City

Fasa

Province

Fars

Postal code

7461686688

Phone

+98 71 5335 0994

Email

FUMS.mansoori@gmail.com

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

Expert

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street address

Ibn Sina square, Fasa

City

Fasa

Province

Fars

Postal code

7461686688

Phone

+98 71 5335 9507

Email

amindakhiliardestani@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Fasa University of Medical Sciences

Full name of responsible person

Sohrab Najafipour

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Virology

Street address

Ibn Sina Square, Fasa.

City

Fasa

Province

Fars

Postal code

7461686688

Phone

+98 71 5335 9507

Email

sohrabnajafipour@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Fasa University of Medical Sciences

Full name of responsible person

Amin Dakhili Ardestani

Position

Expert

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street address

Ibn Sina Square, Fasa.

City

Fasa

Province

Fars

Postal code

7461686688

Phone

+98 71 5335 9507

Email

amindakhiliardestani@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not 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

Amin Dakhili Ardestani, Email Address: Amindakhiliardestani@yahoo.com Contact Number: 09228584505 Address: Fasa University, Ibn Sina Square, Fasa University of Medical Sciences and Health Services

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

1. Contacting the general respondent of study 2. Sending his formal request to respondent 3. The application form in the University Research Council 4. In case of a positive response from the council, it will be provided to the applicant by the ethical principles. 5. The total duration of the process is 20 days.

Comments