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
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Fars
Postal code
4737774617
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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
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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
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Person responsible for scientific inquiries

Contact
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Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Amin Dakhili Ardestani
Position
Expert
Latest degree
Bachelor
Other areas of specialty/work
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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