Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical evaluation of ZAX.1400.C01 in patients with coronavirus in Valiasr Hospital, Fasa, 2021

Protocol summary

Study aim

Evaluation the effect of ZAX.1400.C01 on the course of the disease, symptomatic treatment and reduction of inflammatory mediators in COVID-19 patients hospitalized

Design

A triple-blind clinical trial, two treatment groups and a parallel control group will be performed on 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 admitted to Vali-e-Asr Hospital in Fasa are divided into two groups A and B. The anti-inflammatory effects of ZAX.1400.C01will be evaluated. The study will be blinded at the level of outcome assessor, pathologist and statistical analyst of results. Location: Fasa University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Definitive diagnosis of COVID-19 2. Age between 18 to 65 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. No use Anticoagulants 7. Non-pregnancy and lactation 8. Absence of 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 dissatisfaction 5. History blood pressure

Intervention groups

Divide patients into two similar groups A and B. The treatment group capsules containing ZAX.1400.C01 and the placebo group capsules containing popcorn flour, twice a day. By introducing the plan and justifying the patient, written consent is received.

Main outcome variables

Duration of hospitalization

General information

Reason for update

1. Considering the defined goals for third generation universities, based on the applicability of research in medical sciences, solving a specific problem as a result of research and preserving the intellectual property of ideas and products

Acronym

IRCT registration information

IRCT registration number: **IRCT20210218050404N2**
Registration date: **2021-09-16, 1400/06/25**
Registration timing: **prospective**

Last update: **2021-10-10, 1400/07/18**
Update count: **1**

Registration date

2021-09-16, 1400/06/25

Registrant information

Name

Amin Dakhili Ardestani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 5335 9507

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-27, 1400/07/05

Expected recruitment end date

2021-10-27, 1400/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of ZAX.1400.C01 in patients with coronavirus in Valiasr Hospital, Fasa, 2021

Public title

Clinical evaluation effects of ZAX.1400.C01 in patients with coronavirus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of COVID-19 disease by laboratory test from the patient's lung sputum Age from 18 to 65 years Patient hemoglobin saturation (SPO2) between 85% and 93% Detection of lung involvement percentage by CT scan 20-30 breaths per minute informed consent by participate in the study

Exclusion criteria:

liver and kidney diseases diabetes Pregnancy and lactation anticoagulants administration (aspirin, Plavix, warfarin) hypertension History of allergies to plant products Disagreement of the physician in charge of the patient before randomization Inability of the patient to take oral medication

Age

From **18 years** old to **65 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 will be performed on patients with coronavirus hospitalized in Vali Asr Hospital in Fasa. the patients data will be record (medication regimen, age and sex, severity of disease and severity of symptoms) by individualize code. The relevant expert divides the patients into two similar groups based on the treatment regimen, age group, gender, severity and symptoms, of the disease, and randomly divides one group into group A and one group into group B using the patient. 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

after fulfillment of inclusion criteria the physician will be prescribe A (the drug) or B (placebo) according to the randomized sheet. the prescription will be dispense in the same package. healthcare givers will be unaware about coding dedicated to every patient. 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

Ibn Sina square, Fasa.

City

Fasa

Province

Fars

Postal code

7461686688

Approval date

2021-07-20, 1400/04/29

Ethics committee reference number

IR.FUMS.REC.1400.043

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

Days zero, seven and fourteen after start of the intervention

Method of measurement

ELISA test

2

Description
mortality
Timepoint
Days zero, seven and fourteen after start of the intervention
Method of measurement
clinical check list

3

Description
Duration of hospitalization
Timepoint
Days zero, seven and fourteen after start of the intervention
Method of measurement
clinical check list

4

Description
Need oxygen therapy
Timepoint
Days zero, seven and fourteen after start of the intervention
Method of measurement
clinical check list

5

Description
Equipment used in oxygen therapy
Timepoint
Days zero, seven and fourteen after start of the intervention
Method of measurement
clinical check list

6

Description
Incidence of Acute respiratory distress syndrome (ARDS)
Timepoint
Days zero, seven and fourteen after start of the intervention
Method of measurement
clinical check list

7

Description
fever
Timepoint
Days zero, seven and fourteen after start of the intervention
Method of measurement
clinical check list

8

Description
cough
Timepoint
Days zero, seven and fourteen after start of the intervention
Method of measurement
clinical check list

Secondary outcomes

1

Description
The patient needs to be hospitalized
Timepoint
Days zero, seven and fourteen after start of the intervention
Method of measurement
clinical check list

Intervention groups

1

Description
Intervention group: The medicinal composition of ZAX.1400.C01, in the form of capsules, in two daily doses, is consumed for 14 days.
Category
Treatment - Drugs

2

Description
Control group: The composition of popcorn corn flour, in the form of capsules, is consumed in two daily doses for a period of 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali Asr Hospital, Fasa
Full name of responsible person
Dr. Seyyed Amin Kouhpayeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Other areas of specialty/work
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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

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

No - There is not 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 the study 2. Sending his formal request to the 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 in accordance with the ethical principles. 5. The total duration of the process is 20 days.

Comments