Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Clinical trial of the use of Annual SZ drug in the treatment of patients with Covid-19 disease in Emam Hosein hospital in Tehran.

Protocol summary

Study aim
Treatment and reduction of the course of treatment of patients with Covid-19

Design
Clinical trial with control group, with parallel groups, double-blind, randomized based on hospital admission code, phase 2 on 60 patients

Settings and conduct
In clinical trials, patients are divided into two general categories: The first group is the case group, the second group is the control group. In this study, samples are selected randomly among all clients of Imam Hossein (AS) hospital in Tehran with the symptoms specified in the scoring table. The odd admission codes are allocated into the first group and the even admission codes are allocated into the second group. The number of selected samples in each group is 30 people.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People with COVID-19. Exclusion criteria: none.

Intervention groups
The first group (A): the group treated with the drug Anval SZ + azithromycin. The second group (B): the group that receives treatment based on the country's routine protocol + azithromycin

Main outcome variables
A history of close contact with a person with covid 19 over the past two weeks Oral fever with more than 38 degrees Celsius (or equivalent) or tremors Sore throat or severe feeling of dry throat Dry cough Muscle diffuse pain Clear runny nose Frequent sneezing Headache nausea and vomiting Diarrhea Pain or heaviness in the chest Shortness of breath Acute olfactory disturbance Acute taste disturbance Pulse oximetry less than 93%

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200607047682N1**
Registration date: **2020-07-27, 1399/05/06**
Registration timing: **retrospective**

Last update: **2020-07-27, 1399/05/06**
Update count: **0**

Registration date
2020-07-27, 1399/05/06

Registrant information

Name
Zuhair Saraf

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-09, 1399/03/20

Expected recruitment end date
2020-07-11, 1399/04/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the use of Annual SZ drug in the treatment of patients with Covid-19 disease in Emam Hosein hospital in Tehran.

Public title
Clinical trial of Annual SZ drug in Covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
pationt infected with covid19
Exclusion criteria:
Age
From **16 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to the case and control groups based on the admission codes, so that the even admission code is in the case group and the odd admission code is in the control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice Chancellor for Research and Technology, Shahid Beheshti University
Street address
Velenjak
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2020-06-07, 1399/03/18
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.158

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.2
ICD-10 code description
COVID-19, virus not identified

Primary outcomes

1

Description
Fever - People who have a fever of more than 38 degrees and their score in the questionnaire is 1 or more than one
Timepoint
At the beginning of the study (before the intervention) and 3, 5, 7, 9, 11, 14 days after the start of use
Method of measurement
Mercury thermometer

2

Description
Blood oxygen level 93 and above - People who have a blood oxygen level of less than 93 and get number one in the questionnaire
Timepoint
At the beginning of the study (before the intervention) and 3, 5, 7, 9, 11, 14 days after the start of use
Method of measurement
With digital pulse oximetry device

3

Description
Coughs that have a score of one or more in the questionnaire
Timepoint
At the beginning of the study (before the intervention) and 3, 5, 7, 9, 11, 14 days after the start of use
Method of measurement
Based on the follow-up and the patient's report

4

Description
CRP that has a score of one or more in the questionnaire
Timepoint
On the day of starting (before treatment) 3, 5, 11 after starting treatment
Method of measurement
With the help of laboratory kit and agglutination method

5

Description
HRCT that has a score of one or more based on the questionnaire
Timepoint
The first day before starting treatment and the 30th day

after starting treatment

Method of measurement

With the help of CT scan machine

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group treated with Anval SZ + azithromycin Anval S is a herbal product derived from the herb. The active ingredient is artemisinin, which is used in the treatment of malaria. The dose of TDS is 1-1.5 mg / kg. The time of use is 14 days for definite recovery, this medicine is in the form of oral syrup and is produced by the knowledge-based university of the Health of Living Life, observing all health principles.

Category

Treatment - Drugs

2

Description

The group that receives treatment according to the national routine protocol + azithromycin. The drugs in this group are hydroxychloroquine and keltra. Chloroquine is an anti-malarial drug and the dose is different depending on the phase of the disease and according to the national protocol. Hydroxychloroquine 200 mg daily for 8 days is administered as two stats together and then one every 12 hours for 5 days. About.Cltra tablets (lupinavir / ritonavir): 2 tablets of 50/200 every 12 hours for at least 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hoseyn Hospital

Full name of responsible person

Mohammad Farhbakhsh

Street address

South Shahid Madani Ave

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Province

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1617763141

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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1985717443

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+98 21 23871

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Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Salamat Zendegi Aramesh com1000pany

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hamid Chegini

Position

Faculty

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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