Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effects of Annual SZ drug on modulating immune responses and efficacy against COVID-19 infection: a randomized clinical trial

Protocol summary

Study aim

Evaluation of the effects of Annual SZ drug on modulating immune responses and efficacy against COVID-19 infection Determination of the number and function of lymphocytes along with the average changes of cytokine IL-6, IFNγ and IL-4 in the group receiving the Annual SZ drug compared with the control group

Design

A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial on 80 patients. The stratified randomized block design and sealed envelopes are used for randomization.

Settings and conduct

This study will be conducted in the Payambar Azam Educational, Therapeutic and Research Complex, Bandar Abbas, Iran. Blood samples will be taken before the intervention and on the 7th and 14th days after the intervention and flow cytometry, ELISA, CBC, and CRP tests will be performed. This is a double-blinded study. Blinding of the patient is done by using a placebo. To blind the physician, medication packages are prepared in advance and treating physician does not know the contents of the package.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Signing an informed consent form, Both genders from 20 to 50 years old, Definite infection of COVID-19 Exclusion criteria: Age less than 20 and more than 50 years, Pregnancy, People with Immunodeficiency, cardiac arrhythmia, kidney, liver, metabolic, mental, skin or malignant diseases.

Intervention groups

The intervention group is the group that is currently suffering from COVID-19 and receiving Annual SZ drug. The control group is patients who are currently infected with COVID-19 and are receiving national protocol drugs.

Main outcome variables

CD4, CD8, PD-1, IL-4, IL-6, IFNγ ; Annual SZ effects and effectiveness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201001048894N2**
Registration date: **2022-09-04, 1401/06/13**
Registration timing: **prospective**

Last update: **2022-09-04, 1401/06/13**
Update count: **0**

Registration date

2022-09-04, 1401/06/13

Registrant information

Name

Afshin Samiei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3371 0373

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afshin.samiei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effects of Annual SZ drug on modulating immune responses and efficacy against COVID-19 infection: a randomized clinical trial

Public title
Effects of Annual SZ drug on modulating immune responses and efficacy against COVID-19 infection

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:
Individuals with COVID-19 disease or control group according to specified grouping Both genders from 20 to 50 years old Definite infection with COVID-19 (people whose PCR is positive, HRCT is clear evidence of infection and have common symptoms of moderate disease of Covid-19 Signing an informed consent form

Exclusion criteria:
Age less than 20 years and more than 50 years Pregnancy People with cardiac arrhythmia, kidney, liver, metabolic or malignant diseases Mental or skin diseases (rash, dermatitis, psoriasis) Immunodeficiency diseases Acute patient conditions and severe illness, the patient has shortness of breath, blood oxygen drop and the disease is worsening

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization: In this study, we perform randomization using the method of Stratified Randomized Block Design. In this way, we use even blocks of four. In this section, we have two classes, one class has no history of receiving any vaccine and the other class has already received every dose of Sinopharm vaccine and more than 4 months have passed since their second dose. Then, in these two floors, we perform the randomized block method separately. The purpose of this work is to control the effect of vaccination.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is a double-blind method using a placebo that has the same color, smell, and taste as the original drug but does not have the active ingredient. Also, Pharmaceutical packages will prepare in advance, and each patient will receive a unique code of Pharmaceutical package, so the treating physician does not know the package contents too.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committees of Tarbiat Modares University

Street address
Jalal AleAhmad

City
Tehran

Province
Tehran

Postal code
14115-111

Approval date
2022-08-27, 1401/06/05

Ethics committee reference number
IR.MODARES.REC.1401.112

Health conditions studied

1

Description of health condition studied
Covid-19

ICD-10 code
U07.1

ICD-10 code description
Covid 19 , Virus Identified

Primary outcomes

1

Description
Immune system parameters

Timepoint
Before intervention and 7, 14 days after intervention

Method of measurement
Using flow cytometry and enzyme-linked immunosorbent assay (ELISA) tests

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group is infected with COVID-19 and receives Annual SZ as a treatment. This medicine is a herbal product obtained from the Sweet wormwood plant (with the scientific name Artemisia annua), its active ingredient is artemisinin. It has a concentration of 5mg/ml. The dosage for patients with the moderate stage of the disease is 2mg/kg/day, equivalent to 7 ml of syrup every 6 hours for 14 days. This drug is in the form of an oral syrup and it was produced by the university-based knowledge company of Salamat Zendegi Aramesh.

Category
Treatment - Drugs

2

Description
Control group: This group is infected with COVID-19 and receives the routine drugs of the national protocol as treatment. There is no intervention in this group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Payambar Azam Educational, Therapeutic and Research Complex

Full name of responsible person
Ehsan Soltaninejad Boustani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Bandare-abbas University of Medical Sciences

Proportion provided by this source
60

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

2

Sponsor

Name of organization / entity
Tarbiat Modares University

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
Tarbiat Modares University

Proportion provided by this source
40

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
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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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
only outcome information will be presented
When the data will become available and for how long
3 month after publishing the results
To whom data/document is available
everyone
Under which criteria data/document could be used
not restricted
From where data/document is obtainable
ebtekarm@modares.ac.ir afshin.samiei@gmail.com
What processes are involved for a request to access data/document
sending an e-mail
Comments