

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 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, IFN γ 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, IFN γ ; 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

Email address

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 science

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

Street address

Jomhori Eslami Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915595

Phone

+98 76 3334 7000

Email

Soltaninejad.ehsan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Teymour Aghamolaei

Street address

Shafa Ave.

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915189

Phone

+98 76 3333 7192

Email

research@hums.ac.ir

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

Amir Abdollah zadeh

Street address

Jalal AleAhmad

City

Tehran

Province

Tehran

Postal code

14115-111

Phone

+98 21 8288 2009

Email

Res@modares.ac.ir

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

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Masoumeh Ebtekar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

Street address

Immunology Department, Faculty of Medical Sciences, Trabiati Modares University, Jalal AleAhmad St.

City

Tehran

Province

Tehran

Postal code

14115-111

Phone

+98 21 8288 3891

Email

ebtekarm@modares.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Masoumeh Ebtekar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

Street address

Immunology Department, Faculty of Medical Sciences, Trabiati Modares University, Jalal AleAhmad St.

City

Tehran

Province

Tehran

Postal code

14115-111

Phone

+98 21 8288 3891

Email

ebtekarm@modares.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Afshin Samiei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

Street address

Department of Immunology, School of Medicine, Hormozgan University of Medical Sciences, Emam Hossein Blvd.

City

Bandar Abbas

Province

Hormozgan

Postal code

7919693116

Phone

+98 76 3371 0373

Email

afshin.samiei@gmail.com

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