

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effect of inflawell-syrup on the immune response and the signaling pathway of NF-kB in peripheral blood mononuclear cell in patients with COVID-19: Double blind, placebo-controlled randomized clinical trial

Protocol summary

Study aim

Evaluation of the effect of inflawell syrup on the immune response and the signaling pathway of NF-kB in peripheral blood mononuclear cell in patients with COVID-19

Design

Two arm parallel group randomized double-blind placebo-controlled clinical trial

Settings and conduct

In this study, 40 patients admitted to the infectious ward of Imam Khomeini Hospital due to COVID-19 which confirmed by Polymerase chain reaction test (PCR) , will be evaluated by the researcher based on inclusion and exclusion criteria and will be allocated into the intervention group randomly after completing the consent form.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) COVID-19 patient admitted to the infectious ward of the hospital 2) Age $\geq$ 18 years in both sexes 3) Confirmation of SARS-CoV2 infection based on PCR test and clinical manifestations including: 1. Respiratory distress (breathing $\geq$ 25 times per minute) 2. Percentage of oxygen saturation at rest $\leq$ 92% 4) Early diagnosis (less than or equal to 8 days from the onset of symptoms) 5) Signing the informed consent form
Exclusion criteria: 1) Liver, kidney and heart failure 2) Inability of the patient to consume the oral form 3) Pregnancy and lactation or positive pregnancy test 4) Participate in two or more clinical trials simultaneously

Intervention groups

Intervention group: Patients will receive standard treatments and inflawell syrup (provided By KondorPharma company, Canada) containing standardized powder of Boswellic acids 3 times a day 10 milliliter each time for 14 days (n = 20). Control group: Patients will receive placebo and standard treatments for

14 days (n = 20).

Main outcome variables

Primary outcome: Duration of hospital stay Secondary outcome: Measurement of C-Reactive Protein (CRP) levels in plasma

General information

Reason for update

virawell change to inflawell

Acronym

IRCT registration information

IRCT registration number: **IRCT20170315033086N10**
Registration date: **2021-03-14, 1399/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-12, 1400/03/22**

Update count: **1**

Registration date

2021-03-14, 1399/12/24

Registrant information

Name

Saeed Karima

Name of organization / entity

Shahid Beheshti University of Medical Sciences (SBMU)

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of inflawell-syrup on the immune response and the signaling pathway of NF-kB in peripheral blood mononuclear cell in patients with COVID-19: Double blind, placebo-controlled randomized clinical trial

Public title

Investigation of the efficacy of inflawell syrup on covid-19 patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

COVID-19 patient admitted to the infectious ward of the hospital Age ≥ 18 years in both sexes Confirmation of SARS-CoV2 infection based on PCR test and clinical manifestations including: 1. Respiratory distress (breathing ≥ 25 times per minute) or 2. Percentage of oxygen saturation at rest $\leq 92\%$ Early diagnosis (less than or equal to 8 days from the onset of symptoms) Signing the informed consent form

Exclusion criteria:

Liver, kidney and heart failure Inability of the patient to consume the oral form Pregnancy and lactation or positive pregnancy test Participate in two or more clinical trials simultaneously

AgeFrom **18 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample sizeTarget sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization is designed based on four-sized block randomization procedure. A non-ordered computer sequence list including the intervention, the patient-assigned code (patient code) and the order of recruitment (referral code) is generated by Stata v.15. In each four-sized block there are two drugs and two placebo intervention. There are also six modes for four-sized block layout which used by software in order to

randomization. In addition to the intervention type, the computer list also includes two sets of number. one of them is related to the order of referral sequence or recruitment, which starts from the number one and goes in order. The other set is related to the patient code, which consists of non-consecutive and irregular three-digit numbers, and thus the type of intervention can not be guessed from the order in which patients enter the study. For example, the first person has a three-digit number as a special code. In order to do randomization and concealment, the patient codes are placed inside the concealed envelopes, the sequence of patient referral is written on envelopes. The patient code is also written on the medicine bottle (drug or placebo). In this way, following screening patients based on the inclusion and exclusion criteria and obtaining informed consent, according to the order of referral, the relevant envelope is opened and assigned code is given to the patient and then a bottle with the same code is given to the patient. Thus, the process of participants' allocation into each treatment group is completely random and unpredictable.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient allocation and sequencing are done blindly. All the members of the staff who are involved in performing the enrollment, physicians, nurses and the investigation team as well as patients and their guardians, are masked and uninformed of drug and/or placebo prescription. Referral sequence will be written on the sealed envelopes and patient code will be written in the envelopes and the medication bottles (both drug and placebo). Following patient assessment by the doctor based on inclusion and exclusion criteria, according to the admission sequence, the envelopes with the same number will be opened. According to the patient code, the patients are going to be handed a bottle with the same code. Therefore, the patient is unbeknownst whether the intervention is drug or the placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Koodkiar Dead End, Daneshjoo Blvd., Yemen St., Shahid Chamran Highway, Tehran, Iran

City Tehran Province Tehran Postal code 1985717443 Approval date 2020-10-13, 1399/07/22 Ethics committee reference number IR.SBMU.MSP.REC.1399.311	treatments and placebo syrup, provided by KondorPharma Company (Canada), 3 times a day 10 cc each time for 14 days Category Treatment - Drugs
Health conditions studied <u>1</u> Description of health condition studied COVID-19 ICD-10 code B34.2 ICD-10 code description Coronavirus infection, unspecified	Recruitment centers <u>1</u> Recruitment center Name of recruitment center Imam Khomeini hospital Full name of responsible person Saeed Karima Street address Keshavarz Blvd. Gharib St. Imam Khomeini Hospital Complex, Tehran, Iran City Tehran Province Tehran Postal code 1419733141 Phone +98 21 6658 1587 Email karima@sbmu.ac.ir
Primary outcomes <u>1</u> Description Duration of hospital stay Timepoint Day 7 and 14 after the intervention Method of measurement Number of days	Sponsors / Funding sources <u>1</u> Sponsor Name of organization / entity Shahid Beheshti University of Medical Sciences Full name of responsible person Saeed Karima Street address Koodkiar Dead End, Daneshjoo Blvd., Yemen St., Shahid Chamran Highway, Tehran City Tehran Province Tehran Postal code 1985717443 Phone +98 21 23871 Email info@sbmu.ac.ir
Secondary outcomes <u>1</u> Description C-reactive protein (CRP) Timepoint Baseline and 14 days after intervention Method of measurement ELISA technique	Grant name Vice-Chancellor of Research Affairs, Shahid Beheshti university of medical sciences Grant code / Reference number Is the source of funding the same sponsor organization/entity? No Title of funding source Behbalin Proportion provided by this source 100
Intervention groups <u>1</u> Description Intervention group: patients will receive standard treatments and inflawell syrup (Provided by KondorPharma Co, Canada) containing standardized Boswellic acids powder 3 times a day 10 milliliter each time for 14 days. Category Treatment - Drugs <u>2</u> Description Control group: Placebo receiving group will take standard	

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**

Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Salehi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

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

Data Dictionary

Not applicable

Title and more details about the data/document

Collected IPD will be shared after de-identification of
participants and patients.

When the data will become available and for how long

De-identified data will be available starting from April,
2025

To whom data/document is available

Academics employed at various research/university
institutions and the industry

Under which criteria data/document could be used

No condition is specified.

From where data/document is obtainable

Saeed Karima, Floor 8th, Department of Clinical
Biochemistry, School of Medicine, Shahid Beheshti

University of Medical Sciences, Tehran, Iran. Tel:
+982122439975

What processes are involved for a request to access data/document

The applicant would be asked to provide a written formal

request letter, containing the importance of the data and the project processes. Following the receipt of request letter, the data would be provided in no more than two weeks.

Comments