Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 ≥ 18 years in both sexes 3) Confirmation of SARS-CoV2 infection based on PCR test and clinical manifestations including: 1. Respiratory distress (breathing ≥ 25 times per minute) 2. Percentage of oxygen saturation at rest ≤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)

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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 ≤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
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target 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

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
B34.2
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Duration of hospital stay
Timepoint
Day 7 and 14 after the intervention
Method of measurement
Number of days

Secondary outcomes

1

Description
C-reactive protein (CRP)
Timepoint
Baseline and 14 days after intervention
Method of measurement
ELISA technique

Intervention groups

1

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

2

Description
Control group: Placebo receiving group will take standard treatments and placebo syrup, provided by KondorPharma Company (Canada), 3 times a day 10 cc each time for 14 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Saeed Karima
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Keshavarz Blvd. Gharib St. Imam Khomeini Hospital Complex, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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

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
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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

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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