

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparison effect of N-Chromosome royal jelly, propolis, and mixed honey supplementation on clinical and laboratory findings of COVID-19 patients with standard treatment: a randomized clinical trial

#### Protocol summary

##### Study aim

Comparison effect of N-chromosome royal jelly, propolis and mixed honey supplementation on clinical and laboratory findings of COVID-19 patients with standard treatment: a randomized clinical trial

##### Design

Two arm parallel group randomized trial, randomization will be done using the table of random numbers for 60 admitted patients of confirmed COVID-19 in Masih Daneshvari Hospital from May 2020. Thirty patients will enrolled in case group and 30 ones in control group.

##### Settings and conduct

This study will be performed in Masih Danesvari hospital, Tehran, Iran. 60 covid-19 confirmed patients based on inclusion and exclusion criteria will be divided into two groups (30 in each group) by simple randomization. Patients in control group will be prescribed standard regimen for COVID-19. Patients in experimental group will be prescribed royal jelly, propolis and mixed honey (2 teaspoons of each one, twice a day) for one month and standard regimen for COVID-19. The routine lab data, clinical symptoms and hospitalization period, will be assessed in both groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: -Age 18 to 90 years -No clear psychiatric disorder -Cooperation for medication use -No more than 48 hours have elapsed since admission.  
Exclusion criteria: -Any history of allergies or allergies to honey compounds -Taking warfarin

##### Intervention groups

The case group will be given three products including N-chromosome royal jelly, propolis, and a mixed honey (2 teaspoons of each one, twice a day )with their standard drug treatment for COVID-19. The control group will receive only standard treatment.

##### Main outcome variables

laboratory findings ( ESR,CRP,WBC,Ferritin, Neutophil,

Lymphocyte) , clinical conditions(dyspnea class), cytokine level (IL-6)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200209046427N1**

Registration date: **2020-06-07, 1399/03/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-07, 1399/03/18**

Update count: **0**

##### Registration date

2020-06-07, 1399/03/18

##### Registrant information

##### Name

Shadi Shafaghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2712 2522

##### Email address

shafaghisadi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-30, 1399/03/10

##### Expected recruitment end date

2020-06-30, 1399/04/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison effect of N-Chromosome royal jelly, propolis, and mixed honey supplementation on clinical and laboratory findings of COVID-19 patients with standard treatment: a randomized clinical trial

**Public title**  
Effect of bee products on COVID-19

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
age between 18 to 90 year old without any psychological problem drug consumption compliance hospital admission during recent 48 hours  
**Exclusion criteria:**  
Allergy to honey products warfarin usage

**Age**  
From **18 years** old to **90 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
-Simple randomization -Individual randomization -By using table of random numbers

**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**  
Ethics committee of Shahid Beheshti University of Medical Sciences, Masih Daneshvari Hospital (NRITL)  
**Street address**  
Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran  
**City**  
Tehran

**Province**  
Tehran  
**Postal code**  
1956944413

**Approval date**  
2020-04-14, 1399/01/26

**Ethics committee reference number**  
IR.SBMU.NRITLD.REC.1399.048

## Health conditions studied

### 1

**Description of health condition studied**  
COVID-19 Disease

**ICD-10 code**  
U07.2

**ICD-10 code description**  
COVID-19

## Primary outcomes

### 1

**Description**  
Dyspnea grade

**Timepoint**  
Dyspnea grade before intervention and daily after starting the intervention

**Method of measurement**  
dyspnea grading according to New York heart association classification

### 2

**Description**  
white blood cells (WBC) count

**Timepoint**  
lab test before intervention and 3, and 7 days after intervention

**Method of measurement**  
lab data assessment by blood sample

### 3

**Description**  
Neutrophil to Lymphocyte count

**Timepoint**  
lab test before intervention and 3, and 7 days after intervention

**Method of measurement**  
lab data assessment by blood sample

### 4

**Description**  
Interleukin-6 (IL-6) Level

**Timepoint**  
lab test before intervention and 3, and 7 days after intervention

**Method of measurement**  
lab data assessment by blood sample

## 5

### Description

Anti SARS-Cov-2 IgG Level

### Timepoint

one month after intervention

### Method of measurement

blood sample

## 6

### Description

C-reactive protein (CRP) level

### Timepoint

lab test before intervention and 3, and 7 days after intervention

### Method of measurement

lab data assessment by blood sample

## Secondary outcomes

### 1

#### Description

duration of hospital stay

#### Timepoint

duration of hospitalisation

#### Method of measurement

Hospital records

## Intervention groups

### 1

#### Description

Control group: Standard treatment for COVID-19 according to hospital protocol for admitted patients

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: The case group will be given three products including N-chromosome royal jelly (Caspian Apiaries Company), propolis (Caspian Apiaries Company), and a mixed honey (Caspian Apiaries Company). They should use one teaspoon of each of them, twice a day with water or milk or fruit juice.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Masih Daneshvari Hospital

##### Full name of responsible person

Shadi Shafaghi

##### Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

##### City

Tehran

##### Province

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##### Postal code

1956944413

##### Phone

+98 21 2712 2522

##### Email

pr.nritld@sbmu.ac.ir

##### Web page address

<http://nritld.sbmu.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

##### City

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##### Province

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##### Postal code

19839-63113

##### Phone

+98 21 2243 9331

##### Email

zarghi@sbmu.ac.ir

##### Web page address

<http://en.sbmu.ac.ir/index.jsp?siteid=256&fkeyid=&siteid=24&pageid=13079&siteid=256>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti University of Medical Sciences

#### Proportion provided by this source

100

#### 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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Shadi Shafaghi  
**Position**  
Researcher  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Cardiology  
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shafaghishadi@sbmu.ac.ir

## Person responsible for scientific inquiries

**Contact**  
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Researcher  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**

Shadi Shafaghi  
**Position**  
Researcher  
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Ph.D.  
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shafaghishadi@sbmu.ac.ir

## 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

Yes - There is a plan to make this available

### Title and more details about the data/document

all collected deidentified patient`s documents can be available.

### When the data will become available and for how long

documents files will become available 6 months after publication up to one year

### To whom data/document is available

Documents would be available for people working in academic institutions and people working in businesses after applying to receive it.

### Under which criteria data/document could be used

Documents would be available according to cause of request.

### From where data/document is obtainable

shafaghishadi@yahoo.com

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

It is necessary for the applicant to send an e-mail to the researcher and write the reason for requesting access to the data. If confirmed, the information will be sent within a week.

### Comments