

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

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

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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

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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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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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