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 Daneshvar 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, Neutrophil, 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
shafaghishadi@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
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

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: Standared 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

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pr.nritld@sbmu.ac.ir

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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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Tehran

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19839-63113

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Web page address

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
Shadi Shafaghi
Position
Researcher
Latest degree
Ph.D.
Other areas of specialty/work
Cardiology
Street address
Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran
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Fax
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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