Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 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, propois 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
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

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 rabdomization -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 Univercity 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
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pr.nritld@sbmu.ac.ir
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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
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Tehran
Postal code
19839-63113
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Email
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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 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