Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of Royal Jelly Capsule on reducing the side effects of methylprednisolone treatment in patients with COVID-19

Protocol summary

Study aim

The effect of Royal Jelly Capsule on reducing the side effects of methylprednisolone treatment in COVID-19 patients

Design

In this study, individuals are divided into two groups of intervention 30 and control 30 by random sampling. The first group of the standard diet of ampoules of methylprednisolone 50 mg daily + Royal gel capsules 1000 mg (daily for 7 days) The second group receives the standard diet of ampoules of methylprednisolone 50 mg daily + placebo (daily for 7 days). Blood sugar is also recorded by a glucometer every 8 hours. If the blood sugar rises, the dose and frequency of insulin injections are recorded.

Settings and conduct

60 patients with Covid-19 with positive PCR test and lung involvement are divided into two groups of intervention and control of 30 people. first group receives corticosteroid therapy and Royal Jelly capsules 1000 mg daily for 7 days and the second group receives corticosteroid therapy and placebo.

Participants/Inclusion and exclusion criteria

Inclusion : Patients with positive PCR test under methylprednisolone treatment Exclusion: diabetes, immune deficiency, acute bacterial infectious disease, allergy to bee products

Intervention groups

The first group of the standard diet of ampoules of methylprednisolone 50 mg daily + Royal gel capsules 1000 mg (daily for 7 days) The second group receives the standard diet of ampoules of methylprednisolone 50 mg daily + placebo (daily for 7 days).

Main outcome variables

Blood tests, dose and frequency of insulin and corticosteroids, daily spo2 and severity of disease, weekly clinical signs and inflammatory factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210616051596N1**
Registration date: **2022-01-02, 1400/10/12**
Registration timing: **retrospective**

Last update: **2022-01-02, 1400/10/12**
Update count: **0**

Registration date

2022-01-02, 1400/10/12

Registrant information

Name

Hamidreza pourfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

pourfard.h@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-01, 1400/04/10

Expected recruitment end date

2021-10-02, 1400/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Royal Jelly Capsule on reducing the side effects of methylprednisolone treatment in patients with COVID-19

Public title
Evaluation of the effect of royal jelly on the side effects of methylprednisolone treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with positive PCR test who are treated with methylprednisolone.
Exclusion criteria:
Patients with diabetes, immune deficiency acute bacterial infectious disease allergy to bee products
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of participants to the control and intervention groups was performed using Random Allocation Software. Envelopes were prepared according to the number of participants in the study and were registered on the first envelope number one, the second envelope number 2, etc., and in each envelope, the allocation of each person determined using the mentioned software was placed. The order was opened with the arrival of each envelope for that person and according to the option in the envelope, the person was assigned to one of the intervention or control groups
Blinding (investigator's opinion)
Double blinded
Blinding description
Drugs and placebos are coded by the project manager. Randomization of patients in blocks is done only on the base of of hidden codes, and study participants, physicians, and nurses evaluating the results are blind to intervention and study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
Parastar Aven.Hajar Hospital
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816754633
Approval date
2021-05-31, 1400/03/10
Ethics committee reference number
IR.SKUMS.REC.1400.063

Health conditions studied

1

Description of health condition studied
Covid 19
ICD-10 code
U07.1
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Liver function factors (AST, ALT, ALKP, BILD, BILT)
Timepoint
Daily
Method of measurement
Blood tet

2

Description
Renal function factors (Na, K, Cr and BUN)
Timepoint
Daily
Method of measurement
Blood test

3

Description
Hematological factors (WBC, Hb, PLT)
Timepoint
Daily
Method of measurement
Blood test

4

Description
FBS
Timepoint
Daily
Method of measurement
Blood test

5

Description
Dose and frequency of need for regular insulin (IR)
Timepoint
Daily
Method of measurement
cheklist

6

Description
Dosage and frequency of corticosteroids
Timepoint
daily
Method of measurement
cheklist

7

Description
Clinical symptoms (chills, sore throat, abdominal pain, diarrhea, dyspnea, cough, shortness of breath)
Timepoint
7 day intervals
Method of measurement
Examination and questions

8

Description
Inflammatory factors (ferritin and LDH)
Timepoint
7 day intervals
Method of measurement
Blood test

9

Description
disease severity
Timepoint
daily
Method of measurement
Need medical care, supportive oxygen, need mechanical ventilation

10

Description
spo2
Timepoint
Daily
Method of measurement
Oximetry

Secondary outcomes

1

Description
Duration of hospitalization
Timepoint
Duration of hospitalization due to Covid-19
Method of measurement
File review

Intervention groups

1

Description
Control group: Receiving the standard diet They receive 50 mg of methylprednisolone ampoules daily + placebo (daily for 7 days).
Category
Treatment - Drugs

2

Description
Intervention group: Standard diet ampoules of methylprednisolone 50 mg daily + Royal gel capsules 1000 mg (daily for 7 days)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Hospital, Shahrekord
Full name of responsible person
Akbar Soleimani
Street address
Parastar Aven
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hamidhrpus@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person

Mehraban Sadeghy
Street address
Parastar Aven
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hamidhrpus@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Hamidreza Pourfard
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

2021-2022

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

I have not decided yet

From where data/document is obtainable

I have not decided yet

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

I have not decided yet

Comments