Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of the Effect of Royal Jelly on the Healing Process of Patients Infected with Hepatitis B Virus and the Expression of Toll-like Receptors

Protocol summary

Study aim

Determining the effect of oral administration of Royal Jelly on the recovery of Hepatitis B and its effect on the innate immune factors

Design

Clinical trial containing the patients who infected with Hepatitis B virus of both sexes in the age range of 20 to 55 years with 50 people in each group in the period from May to August 2021.

Settings and conduct

The present study will be performed on the patients infected by hepatitis B. Patients referred to Kerman Medical Sciences Hospital will be under the supervision of a specialist and will complete the consent form before entering the study. Before receiving Royal Jelly, 5 ml of blood sample will be taken. Each patient will then receive one gram of Royal Jelly orally daily for one month. After one month, blood samples are taken from each patient again. On all blood samples before and after oral administration of Royal Jelly, tests for determining the load of the virus with a special hepatitis B kit will be performed by the TaqMan real-time PCR assay. Also, the expression of all Toll-like receptors will be evaluated using the SYBR Green based real-time PCR assay before receiving Royal Jelly. The researcher will measure the above cases in relation to the blind study. The results will be statistically analyzed.

Participants/Inclusion and exclusion criteria

Including criteria: Having a Hepatitis B infection for more than six months Exclusion criteria: Infected by other viruses, Suffering from immune related diseases, Receiving immune affected drugs

Intervention groups

The test groups are the infected patients with Hepatitis B

Main outcome variables

Hepatitis B, Royall Jelly, Gene expression, Toll-like receptors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210329050786N1**
Registration date: **2021-05-09, 1400/02/19**
Registration timing: **prospective**

Last update: **2021-05-09, 1400/02/19**
Update count: **0**

Registration date

2021-05-09, 1400/02/19

Registrant information

Name

Maryam Naghib

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3244 2523

Email address

mnaghib1359@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Effect of Royal Jelly on the Healing Process of Patients Infected with Hepatitis B Virus and the Expression of Toll-like Receptors

Public title
The Effect of Royal Jelly on the recovery of Hepatitis B patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Infected with Hepatitis B for more than six months
Exclusion criteria:
Infected by other viruses Suffering from immune related diseases Receiving drugs that affect the immune system
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
1
Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **2**
Five ml of blood before and after receiving Royal Jelly orally
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
The sample tests will be analyzed by blind review
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Valieasr Blvd.,
City
Kerman
Province
Kerman
Postal code
7635151167
Approval date
2019-06-05, 1398/03/15
Ethics committee reference number
IR.kmu.REC.1398.092

Health conditions studied

1

Description of health condition studied
Hepatitis B
ICD-10 code
B16
ICD-10 code description
Acute hepatitis B

Primary outcomes

1

Description
Gene expression of Toll-like receptors will be measured in the Hepatitis B infected patients before and after oral administration of Royal Jelly.
Timepoint
Before and after taking Royal Jelly orally
Method of measurement
Real time PCR assay

Secondary outcomes

empty

Intervention groups

1

Description
In this study, 50 Hepatitis B virus infected patients will be treated with oral administration of royal jelly at a rate of one gram per day for a month. Royal jelly will be used as an intervention agent. Royal jelly will be prepared from beekeepers in Iran. Before and after oral administration of Royal Jelly, the virus copy numbers will be evaluated by the TaqMan real-time PCR assay and the gene expression of toll-like receptors will be examined using the SYBR Green based real-time PCR assay too. The results will be compared before and after oral administration of Royal Jelly.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kerman Special Disease hospital

Full name of responsible person
Maryam Naghib
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No.78, Shahid Rajaei Ave.,
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7719617996
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Ashraf Kariminik
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akarimish@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University, Kerman Branch
Proportion provided by this source
100
Public or private sector
Private
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
Islamic Azad University
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Maryam Naghib
Position
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There are no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available