

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Investigating the Effect of Royal Jelly on the expression of Some Members of S100, Apoptosis, Inflammasomes and Chemokines Families in the Patients with Chronic HBV Infections

Protocol summary

Study aim

Determining the effect of oral administration of Royal Jelly on the gene expression of S100A10, S100A9, S100A4, MANGO, OCTB4, BAX, NLRP1, NLRP3, ASC, CCL2, CCL3 and CCL8 molecules

Design

Clinical trial containing the patients who infected with Hepatitis B virus of both sexes in the age range of 20 to 60 years in the period from August to December 2021, double-blind, randomized and phase 1 on 50 patients. The oral administration period of Royal Jelly is one month

Settings and conduct

Patients with Hepatitis B 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, the expression of the gene expression of S100A10, S100A9, S100A4, MANGO, OCTB4, BAX, NLRP1, NLRP3, ASC, CCL2, CCL3 and CCL8 molecules 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.

Participants/Inclusion and exclusion criteria

Infected with Hepatitis B

Intervention groups

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. Before and after oral administration of Royal Jelly, the gene expression of some immune molecules will be examined using the SYBR Green based

real-time PCR assay . The results will be compared before and after oral administration of Royal Jelly in infected patients.

Main outcome variables

Gene expression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210620051640N1**

Registration date: **2021-08-26, 1400/06/04**

Registration timing: **prospective**

Last update: **2021-08-26, 1400/06/04**

Update count: **0**

Registration date

2021-08-26, 1400/06/04

Registrant information

Name

Morteza Bahaaldin-Beygi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3347 8017

Email address

beygi_morteza@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-10, 1400/06/19

Expected recruitment end date

2022-03-10, 1400/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Royal Jelly on the expression of Some Members of S100, Apoptosis, Inflammasomes and Chemokines Families in the Patients with Chronic HBV Infections

Public title

The Effect of Royal Jelly on Gene Expression of Some Immune Factors in People Infected with Hepatitis B

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

No age limit

Gender

Both

Phase

1

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget 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**

Islamic Azad University, Kerman Branch (Biomedical Research Ethics Committee)

Street address

Valiasr Ave,

City

Kerman

Province

Kerman

Postal code

7635131167

Approval date

2021-05-12, 1400/02/22

Ethics committee reference number

IR.IAU.Kerman.REC.1400.010

Health conditions studied**1****Description of health condition studied**

Hepatitis B

ICD-10 code

B18

ICD-10 code description

Chronic viral hepatitis

Primary outcomes**1****Description**

Gene expression of some molecules of S100 families, apoptosis, inflammation and chemokines is measured in patients with hepatitis B 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 gene expression of some molecules of the S100 family, apoptosis, inflammation, and chemokines 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Full name of responsible person

Morteza Bahaadin Beygi

Position

Ph.D. Student

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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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 is 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