

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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, Royal 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

**Street address**

No.78, Shahid Rajaei Ave.,

**City**

Kerman

**Province**

Kerman

**Postal code**

7719617996

**Phone**

+98 34 3271 2001

**Email**

mnaghib1359@gmail.com

**Position**

pH.D student of Microbiology

**Latest degree**

Master

**Other areas of specialty/work**

Microbiology

**Street address**

No.8, Jahad Blvd.,

**City**

Kerman

**Province**

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7619736468

**Phone**

+98 34 3244 2523

**Email**

mnaghib1359@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ashraf Kariminik

**Street address**

Valieasr Blvd.,

**City**

Kerman

**Province**

Kerman

**Postal code**

7635131167

**Phone**

+98 34 3132 1776

**Email**

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

**Full name of responsible person**

Maryam Naghib

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Maryam Naghib

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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