# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 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**
Islamic Azad University,Kerman Branch(Biomedical Research Ethics Commitee)
**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**
Morteza Bahaadin Beygi
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Valiasr Ave,
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beygi_morteza@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Islamic Azad University
**Full name of responsible person**
Ashraf Kariminik
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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**
Microbiology
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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)**
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