

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effect of levamisole co-administration on the level of immune response to hepatitis B vaccine in healthy individuals.

#### Protocol summary

##### Summary

Healthy family members of hepatitis B patients who have not previously received the hepatitis B vaccine and who test negative for HBs Ag and HBs Ab are recruited in a randomized fashion into a double-blind clinical trial. The subjects are randomly divided into an intervention group and a control group. Those in the intervention group receive the hepatitis B vaccine in three doses at 0, 1, and 6 months co-administered with levamisole tablet 50mg, while those in the control group are given the hepatitis B vaccine with placebo. The HBs Ab levels are then measured one month after the final dose of the vaccine and the results are compared in order to evaluate the effect of levamisole co-administration on the degree of response to the hepatitis B vaccine.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014110618915N2**

Registration date: **2014-11-19, 1393/08/28**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-11-19, 1393/08/28

##### Registrant information

###### Name

Mousalreza Hosseini

###### Name of organization / entity

Mashhad University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 80 1274 2513

##### Email address

hoseinimr@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashad University Of Medical Sciences

##### Expected recruitment start date

2014-04-27, 1393/02/07

##### Expected recruitment end date

2014-12-21, 1393/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of levamisole co-administration on the level of immune response to hepatitis B vaccine in healthy individuals.

##### Public title

The role of levamisole co-administration hepatitis B vaccine in immunization.

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: 16 years old and older without a history of a chronic disease or previous hepatitis B vaccination. Exclusion criteria: current smoking and/or addiction to any form of drug; body mass index above 30 kg/m<sup>2</sup>; previous history of hepatitis B vaccination or infection; positive testing for HBs Ag or HBs Ab; any current chronic and/or acute disease.

##### Age

From **16 years** old to **70 years** old

##### Gender

Both

**Phase**

3

**Groups that have been masked***No information***Sample size**Target sample size: **217****Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Mashad University Of Medical Sciences

**Street address**Goreyshi Building, Daneshgah Street, Mashad  
University Of Medical Sciences**City**

Mashhad

**Postal code****Approval date**

2014-04-26, 1393/02/06

**Ethics committee reference number**

920550

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

Need for immunization against viral hepatitis

**ICD-10 code**

Z24.6

**ICD-10 code description**Persons with potential health hazards related to  
communicable diseases**Primary outcomes****1****Description**Response rate to the hepatitis B vaccine when  
levamisole is co-administered**Timepoint**HBs Ab levels are measured one month after the final  
dose of the vaccine**Method of measurement**

Laboratory

**Secondary outcomes**

empty

**Intervention groups****1****Description**Placebo: administered orally from one week prior to  
every hepatitis-B vaccination dose to one week after.**Category**

Treatment - Drugs

**2****Description**Intervention: levamisole administered orally from one  
week prior to every hepatitis-B vaccination dose to one  
week after.**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Mousalreza Hosseini

**Street address**Internal Department, Ghaem Hospital, Ahmadabad  
Street**City**

Mashhad

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

Mashad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Tafaghodi

**Street address**Ghoreishi Building, Danseshgah Street, Research Vice  
Chanecellary, Mashhad University of Medical Sciences**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Mashad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Mashad University Of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*