Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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Iran (Islamic Republic of)
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+98 80 1274 2513
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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/m2; 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
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Ghoreishi Biulding, 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
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Person responsible for updating data

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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