Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Efficacy of adjuvant levamisole user and levamisole non-user with hepatitis B vaccination in vaccine non-responders health care workers

Protocol summary

Summary

The purpose of this study is evaluating the efficacy of levamisole adjuvant plus hepatitis B vaccination in health care workers which are non-responders to vaccination. This study is a double blind clinical trial. 116 qualified health employees among persons having records in Imam Reza hospital infection control committee were selected and divided systematic randomly into two groups of intervention and control. Vaccination in both groups with 20 micrograms of hepavax into deltoid was done at 0-1-2 months. In intervention group, 50 mgr levamisole was used orally twice daily during 6 days before till 6 days after receiving each dose of vaccine and control group was given placebo drug instead of levamisole as same. Second dose of vaccine injection with 50 mg drug was used twice a day and 1 month after the third dose, the rate of their antibody variation was used. Inclusion criteria: employees who have a history of hepatitis B vaccination and they aren't immunized against this disease (HBsAb under 10); completing an informed consent form. Exclusion criteria: employees with history or facing with positive HBsAg and HBcAb hepatitis

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012110417N3**
Registration date: **2014-03-17, 1392/12/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-03-17, 1392/12/26

Registrant information

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of adjuvant levamisole user and levamisole non-user with hepatitis B vaccination in vaccine non-responders health care workers

Public title

Effect of levamisole adjuvant plus hepatitis B vaccine in vaccine non-responders health care workers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: employees who have a history of hepatitis B vaccination and they aren't immunized against this disease (HBsAb under 10); completing an informed consent form. Exclusion criteria: employees

with history or facing with positive HBsAg and HBcAb hepatitis

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti bulvard, Vice Chancellor for Research Affairs

City
Kermanshah

Postal code
6714673159

Approval date
2013-11-20, 1392/08/29

Ethics committee reference number
35856/7/420/پ

Health conditions studied

1

Description of health condition studied
Hepatitis B vaccination

ICD-10 code
Z24.6

ICD-10 code description
Need for immunization against viral hepatitis

Primary outcomes

1

Description
Antibody titer to hepatitis B

Timepoint
One month after starting intervention - three months after the first intervention - one month after the last intervention

Method of measurement
Laboratory measurement of antibody titer

Secondary outcomes

1

Description
Side effects of medication or placebo

Timepoint
During the study period

Method of measurement
Interview

Intervention groups

1

Description
In intervention group, 50 mgr levamisole is used orally twice daily during 6 days before till 6 days after receiving each dose of vaccine (20 micrograms hepavax vaccine into deltoid at 0-1-2 months)

Category
Treatment - Drugs

2

Description
The control group was given placebo instead of levamisole

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Research Center for Liver Disease and Hepatitis

Full name of responsible person
Dr. Armin Vazirian

Street address
Research Center for Liver Disease and Hepatitis, Imam Reza hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
koroush hamzehee
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Building No.2, Shahid Behesht bulvardi, Vice Chancellor for Research Affairs
City
Kermanshah

Grant name
38275
Grant code / Reference number
38275
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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

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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