

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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

Name

Babak Sayad

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1823 3957

Email address

babaksayad@kums.ac.ir

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 boulevard, 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

City

Kermanshah

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

koroush hamzehee

Street addressBuilding 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****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Armin Vazirian

Position

Assistant of Infection Diseases

Other areas of specialty/work**Street address**Liver Disease and Hepatitis Research Center,Imam
Reza Hospital**City**

Kermanshah

Postal code**Phone**

+98 83 1427 6330

Fax**Email**

arminawa@yahoo.com

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

Kermanshah University of Medical Sciences

Full name of responsible person

Babak Sayad

Position

Associate Professor of Infectious Diseases

Other areas of specialty/work**Street address**Liver Disease and Hepatitis Research Center,Imam
Reza Hospital**City**

Kermanshah

Postal code**Phone**

+98 83 1427 6342

Fax**Email**

babaksayad@kums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Armin Vazirian

Position

Assistant of Infection Diseases

Other areas of specialty/work**Street address**Liver Disease and Hepatitis Research Center,Imam
Reza Hospital**City**

Kermanshah

Postal code**Phone**

+98 83 1427 6342

Fax**Email**

arminawa@yahoo.com

Web page address**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*