

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

A randomized placebo-controlled double blind study to evaluate intradermal vaccination in hepatitis B healthy carriers to eliminate virus

Protocol summary

Summary

HBsAg positive patients would be referred from laboratories in all over Guilan state and would be evaluated for Inclusion and Exclusion criteria. These subjects will be allocated to study groups using simple randomization. Cases receive six monthly doses of hepatitis B recombinant vaccine (Heberbiovac HB) in Intradermal (id) form. Controls receive no vaccine but normal saline as a placebo. We will compare cases with controls according to their response to vaccination. The response to vaccination is defined as loss of HBsAg and appearance of anti-HBs, loss of HBeAg, undetectable HBV-DNA and persistence of normal ALT levels in the post vaccination period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706131155N3**

Registration date: **2008-11-10, 1387/08/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2008-11-10, 1387/08/20

Registrant information

Name

Farahnaz Joukar

Name of organization / entity

Guilan University of Medical Sciences,
Gastrointestinal and liver disease Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 1553 5116

Email address

info@gldrc.org

Recruitment status

Recruitment complete

Funding source

gastrointestinal and liver disease research center
(GLDRC)

Expected recruitment start date

2007-01-29, 1385/11/09

Expected recruitment end date

2009-01-29, 1387/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized placebo-controlled double blind study to evaluate intradermal vaccination in hepatitis B healthy carriers to eliminate virus

Public title

The efficacy of specific hepatitis B virus (HBV) vaccination, in Intradermal form, in healthy carriers of HBV to eliminate virus

Purpose

Treatment

Inclusion/Exclusion criteria

Including hepatitis B healthy carriers (positive HBsAg with normal alanine transaminase level). Excluding D.M or other autoimmune diseases, chronic or serious medical diseases, malnutrition, positive for anti-HIV, anti-HCV and Anti-HDV, pregnancy, receiving any antiviral medication, alcohol intake daily, refusing to give informed consent and so increase in ALT or getting a serious disease during the project and volunteer refusing to continue.

Age

No age limit
Gender
Both
Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **94**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1
Registry name
Secondary trial Id
Registration date
2017-11-21, 1396/08/30

Ethics committees

1
Ethics committee
Name of ethics committee
gastrointestinal and liver disease research center (GLDRC)
Street address
gastrointestinal and liver disease research center (GLDRC) - Razi hospital- Sardar Jangal ave.
City
Rasht
Postal code
Approval date
2006-12-30, 1385/10/09
Ethics committee reference number
31/3/85/201

Health conditions studied

1
Description of health condition studied
Hepatitis B
ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
undetectable HBV-DNA
Timepoint
6th month and 12th month
Method of measurement
PCR

2
Description
loss of HBsAg and appearance of anti-HBs
Timepoint
6th month and 12th month
Method of measurement
ELIZA test

Secondary outcomes

1
Description
clinical situation and possibly side effects
Timepoint
monthly
Method of measurement
clinically

Intervention groups

empty

Recruitment centers

1
Recruitment center
Name of recruitment center
gastrointestinal and liver disease research center (GLDRC)
Full name of responsible person
Dr.Fariborz Mansour-Ghanaei
Street address
gastrointestinal and liver disease research center (GLDRC), Razi hospital, Sardar Jangal Ave.
City
Rasht

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
guilan university of medical sciences
Full name of responsible person
Farahnaz Joukar
Street address
gastrointestinal and liver disease research center (GLDRC) - Razi hospital - Sardar Jongal Ave.
City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

guilan 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

gastrointestinal and liver disease research center (GLDRC)

Full name of responsible person

Farahnaz Joukar

Position

assistant of gastrointestinal and liver disease research center (GLDRC)

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

gastrointestinal and liver disease research center (GLDRC)

Full name of responsible person

Dr.Fariboraz Mansou-Ghanaei

Position

Head / Full Professor of Internal Medicine & Gastroenterology

Other areas of specialty/work

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Person responsible for updating data

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gastrointestinal and liver disease research center (GLDRC)

Full name of responsible person

Dr.Helia Valaee-Barhagh

Position

researcher

Other areas of specialty/work

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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