

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effects of different doses of HBV vaccine on viral load of chronic carrier state of HBV

Protocol summary

Summary

(1) Objectives: To determine the effects of different doses of HBV vaccine on viral load of chronic carrier state of HBV (2) Design: Randomized controlled Trial (3) Setting and conduct: At first, 120 patients in chronic carrier state of HBV will be randomly classified in 4 groups each containing 30 patients. Both physician and patient will be blind about this classification. The first group will be treated with placebo (at start, month 1 and month 6). The 2nd group will be treated with 1 dose of HBV vaccine (at start, month 1 and month 6). The 3rd groups will be treated 2 doses of HBV vaccine (at start, month 1 and month 6). The 4th group will be treated with 2 doses of HBV vaccine (at start, month 1, month 2 and month 6). HBV viral load will be assessed in two stages (at start and 1 month after the last dose) by real time PCR method. Also clinical examinations will be done in three stages (at start, month 2 and 1 month after the last dose). Data will be analyzed and the effects of different doses of vaccine will be assessed on HBV viral load. (4) Participants including major eligibility criteria: Inclusion criteria: Age between 20 and 65 years, Absence of clinical manifestations of hepatitis B infection, ALT= \leq 40; Exclusion criteria: ALT $>$ 40, Presence of clinical manifestations of hepatitis B infection. (5) Intervention: Hepatitis Vaccine (6) Main outcome measures variables: HBV viral load

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202259124N1**
Registration date: **2012-08-09, 1391/05/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-09, 1391/05/19

Registrant information

Name

Gholamreza Roshandel

Name of organization / entity

Golestan University of Medical Sciences/ Golestan Research Center of Gastroenterology and Hepatology

Country

Iran (Islamic Republic of)

Phone

+98 17 3225 1910

Email address

roshandel@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Golestan University of Medical Sciences

Expected recruitment start date

2007-10-23, 1386/08/01

Expected recruitment end date

2010-10-23, 1389/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of different doses of HBV vaccine on viral load of chronic carrier state of HBV

Public title

Effects of vaccine in treatment of Hepatitis b patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 20 and 65 years; Absence

of clinical manifestations of hepatitis B infection;
ALT= <40 Exclusion criteria: ALT >40 ; Presence of clinical
manifestations of hepatitis B infection

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Ethics committee of Golestan University of Medical
Sciences

Street address

Kilometer 5, Gorgan-Sari road

City

Gorgan

Postal code

Approval date

2007-11-11, 1386/08/20

Ethics committee reference number

4671

Health conditions studied

1

Description of health condition studied

Hepatitis B virus carrier

ICD-10 code

Z22.5

ICD-10 code description

Hepatitis B surface antigen [HBsAg] carrier

Primary outcomes

1

Description

HBV viral load

Timepoint

Before first dose of vaccine and 1 month after last dose of
vaccine

Method of measurement

Real time PCR of serum samples

Secondary outcomes

1

Description

levels of ALT

Timepoint

Start of the study; months 2 and 7

Method of measurement

Serologic examination

Intervention groups

1

Description

Placebo at start, month 1 and month 6

Category

Placebo

2

Description

1 dose of HBV vaccine at start, month 1 and month 6

Category

Treatment - Drugs

3

Description

2 dose of HBV vaccine at start, month 1 and month 6

Category

Treatment - Drugs

4

Description

2 doses of HBV vaccine at start, month 1, month 2 and
month 6

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Nabavi clinic of 5 Azar hospital

Full name of responsible person

Dr Beshnaz Khodabakhshi

Street address

5 Azar hospital, 4th Azar alley

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Golestan University of Medical Sciences

Full name of responsible person

Dr Mohsen Aarabi

Street address

Falsafi educational complex, Gorgan-Sari road, Gorgan

City

Gorgan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Golestan 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

Golestan University of Medical Sciences

Full name of responsible person

Dr Abdolvahab Moradi

Position

Virologist/ Associate Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

Speciality in infectious disease/ Associated Professor

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Position

PhD Student in Epidemiology

Other areas of specialty/work

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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

