

# 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**

Gorgan

## 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**

**Street address**

Department of microbiology, Falsafi educational complex, Gorgan-Sari road, Gorgan

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Golestan University of Medical Sciences

**Full name of responsible person**

Dr Behnaz Khodabakhshi

**Position**

Speciality in infectious disease/ Associated Professor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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Golestan University of Medical Sciences

**Full name of responsible person**

Dr Gholamreza Roshandel

**Position**

PhD Student in Epidemiology

**Other areas of specialty/work**

**Street address**

Golestan Research Center of Gastroenterology and Hepatology, Shahid Nabavi clinic, 4th Azar alley, 5th Azar street, Gorgan

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roshandel@goums.ac.ir, roshandel\_md@yahoo.com

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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*

