Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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=<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 firt 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

City

Gorgan

Postal code

Phone

+98 17 1442 1651

Fax

Email

abmoradi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Golestan University of Medcial Sciences

Full name of responsible person

Dr Behnaz Khodabakhshi

Position

Speciality in infectious disease/ Associated Professor

Other areas of specialty/work

Street address

5th Azar hospital, 5th Azar street, Gorgan

City

Gorgan

Postal code

Phone

+98 17 1233 0230

Fax

Email

behkhoda@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

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

City

Gorgan

Postal code

Phone

+98 17 1234 0835

Fax

+98 17 1236 9210

Email

roshandel@goums.ac.ir, roshandel_md@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*