

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the Efficacy and Safety of Hepatitis B vaccine of Pasteur Institute of Iran and Cuban Heber biotec Company's in Iranian healthy volunteers

Protocol summary

Summary

Aim: Comparing the Efficacy and Safety of Hepatitis B vaccine of Pasteur Institute of Iran and Cuban Heber biotec Company's in Iranian healthy volunteers Study Design: Randomized, non-controlled with placebo, single center, Phase 2 clinical trial, Study Population: Iranian healthy volunteers in Tehran Healthy volunteers completed inform consent Exclusion criteria: HBsAg+ or HBcAb+ patients Previous incubation of hepatitis B vaccine or serum HBsAb >10 mIU/ml before the first dose of vaccine incubation Patients with: Thalassemia, any malignancies, Immunodeficiency, HIV, DM, Liver failure and dialysis patients Sample size:440 intervention: Incubation of hepatitis B vaccine of Pasteur Institute of Iran and Cuban Heber biotec Company's in 3 course Initial outcome: Change in HBsAb level

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109113307N5**
Registration date: **2011-09-19, 1390/06/28**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-09-19, 1390/06/28

Registrant information

Name

Seyed Moayed Alavian

Name of organization / entity

BRCGL-THC

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 2072

Email address

info@brcgl.ir

Recruitment status

Recruitment complete

Funding source

Iran's Pasteur Institute (IPI)

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Efficacy and Safety of Hepatitis B vaccine of Pasteur Institute of Iran and Cuban Heber biotec Company's in Iranian healthy volunteers

Public title

Comparing the Efficacy and Safety of Hepatitis B vaccine of Pasteur Institute of Iran and Cuban Heber biotec Company's in Iranian healthy volunteers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Healthy volunteers completed inform consent Exclusion criteria: HBsAg+ or HBcAb+ patients Previous incubation of hepatitis B vaccine or serum HBsAb >10 mIU/ml before the first dose of vaccine incubation Patients with: Thalassemia, any malignancies, Immunodeficiency, HIV, DM, Liver failure and dialysis patients

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **440**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Baqyatallah University of Medical Sciences

Street address

Baqyatallah University of Medical Sciences, Mollasdra Ave., Vanak Squ

City

Tehran

Postal code

19395-5487

Approval date

2010-02-28, 1388/12/09

Ethics committee reference number

340/22/س

Health conditions studied**1****Description of health condition studied**

Acute Hepatitis B

ICD-10 code

B16

ICD-10 code description

Acute hepatitis B

2**Description of health condition studied**

Chronic (viral) hepatitis B

ICD-10 code

B18.1

ICD-10 code description

Chronic (viral) hepatitis B

Primary outcomes**1****Description**

HBsAb serum titre

Timepoint

Respectively, one, six and seven month after incubation of first vaccine

Method of measurement

ELISA test

Secondary outcomes**1****Description**

Vaccination adverse events

Timepoint

Respectively, one, six and seven month after incubation of first vaccine

Method of measurement

Based on history and measured blood biochemical variables

Intervention groups**1****Description**

Hepatitis B vaccine produced by Pasteur Institute of Iran (intervention group) in 3 course. Month 0, month 1 and month 6.

Category

Prevention

2**Description**

Hepatitis B vaccine produced by Heber Biotech Institute of Cuba (Control group) in 3 course. month 0, month 1, and month six.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Baqyatallah University of Medical Sciences

Full name of responsible person

Mostafa Shafiei

Street address

Ground Floor of Baqiyatallah Hospital, Baqiyatallah Medical University, Mollasdra Ave., Vanak Squ

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pasteur Institute of Iran (IPI)

Full name of responsible person

Hanieh Mahdiani

Street address

NO. 69, Pasteur Ave

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pasteur Institute of Iran (IPI)

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

Baqiyatallah Research Center for Gastroenterology and Liver Diseases

Full name of responsible person

Mostafa Shafiei

Position

M.D.

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