

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparing efficacy of two strategies of HBV vaccination in HIV infected patients

Protocol summary

Summary

Limited studies were carried out on effective strategy of HBV vaccination in HIV positive patients but still appropriate method was not determined. Due to importance of this issue and lack of consensus on a unique schedule on HBV vaccination of HIV positive patients, we performed this study to asses two modified HBV vaccination Schedule in HIV positive patients. 150 HIV cases will be enrolled in the study and randomly divided into 3 groups. In 50 cases vaccination with double dose of HB vaccine (40 µg) in 4 times (0,1,2,6 months) intramuscularly, in 50 cases low dose intradermal (4 µg) in 4 times (0,1,2,6 months) and in 50 subjects routine vaccination (20 µg) in 3 times (0,1,6 months) intramuscularly would be administered. One month after last dose of vaccine, anti-HBs titre will be assessed and 3 groups will be compared. In non-responder cases of intradermal group, 2 additional doses of intradermal vaccine would be administered with 2 weeks interval and 1 month after the last dose, anti-HBs titre will be assessed. 4 months after the last dose of HBV vaccine, 3 groups will be compared regarding the persistence of anti-HBs titres.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122415878N2**
Registration date: **2014-01-12, 1392/10/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-12, 1392/10/22

Registrant information

Name

Amitis Ramezani

Name of organization / entity

Pasteur Institute of Iran

Country

Iran (Islamic Republic of)

Phone

+98 21 6696 8852

Email address

amitisramezani@hotmail.com

Recruitment status

Recruitment complete

Funding source

Pasteur Institute of Iran

Expected recruitment start date

2012-12-05, 1391/09/15

Expected recruitment end date

2015-08-06, 1394/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy of two strategies of HBV vaccination in HIV infected patients

Public title

Comparing 2 methods of HBV vaccination in HIV positive patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: HIV positive adults referring to Iranian research center for HIV/AIDS with negative hepatitis B markers (HBsAg, anti-HBc, anti-HBs), no history of HBV vaccination, CD4 count more than 200 cells/mm³ and

negative pregnancy test. Exclusion criteria: Patients with immunosuppression (not related to HIV) like organ recipients, chemotherapy, using systemic steroids, hemopathy, cancer, opportunistic infection, splenectomy, renal failure, cases receiving other vaccines 1 month before study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Pasteur Institute of Iran

Street address

Pasteur Ave.

City

Tehran

Postal code

13164

Approval date

2012-11-20, 1391/08/30

Ethics committee reference number

91/0201/7325

Health conditions studied

1

Description of health condition studied

Human Immunodeficiency Virus

ICD-10 code

Z21-Y59.0

ICD-10 code description

Asymptomatic human immunodeficiency virus [HIV] infection status- Viral vaccines

Primary outcomes

1

Description

HBV vaccination

Timepoint

1 and 4 months after the last dose of HBV vaccine

Method of measurement

checking of anti-HBs titre

Secondary outcomes

empty

Intervention groups

1

Description

Double dose of HB vaccine (40 µg) in 4 times (0,1,2,6 months) intramuscularly

Category

Prevention

2

Description

low dose of HBV vaccine intradermaly (4 µg) in 4 times 0,1,2,6 months

Category

Prevention

3

Description

Routine HBV vaccination (20 µg) in 3 times 0,1,6 months, intramuscularly

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Research Center for HIV/ AIDS

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pasteur Institute of Iran

Full name of responsible person

Amitis Ramezani

Street address

Clinical Research Dept., Pasteur Institute of Iran, No 69, Pasteur Ave.

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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

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**

Pasteur Institute of Iran

Full name of responsible person

Dr Amitis Ramezani

Position

Infectious Diseases Specialist, Academic Member (Associate Professor)

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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

Data Dictionary

empty