

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Immune response to hepatitis B vaccine among isolated HBC Ab positive patients who infected with HIV

Protocol summary

Summary

Isolated HBCAb in patients with HIV infection may occur for different reasons including 1) HBsAg is not measurable despite, the patient is still infected for hepatitis B 2) the patient is improved but HBsAb is not detectable and finally 3) The result of HBcAb is a false positive. This study will be done to investigate the effect of the hepatitis B vaccine among HBcAb positive patients with HIV and as a result, to differentiate between patients with hepatitis B of two other groups. All of HIV-positive patients who have Isolated HBcAb (about 30 person) will be studied. And Those which are positive for HBsAg, HBsAb and HBV DNA PCR are excluded. All patients vaccinated for the first time, and two weeks to a month later, they are tested for HBsAb titer. In the patients who have HBsAb titer above 10 iu/ml, this study will be completed and if result of HBsAb is less than 10, They Should receive the next doses of vaccine and then will be retested.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072023251N1**

Registration date: **2015-08-12, 1394/05/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-12, 1394/05/21

Registrant information

Name

Mohammad Mahdi Majzoobi

Name of organization / entity

Hamadan University of Medical Sciences, School of

Medicine

Country

Iran (Islamic Republic of)

Phone

+98 818271091

Email address

mahdi.majzoobi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Immune response to hepatitis B vaccine among isolated HBC Ab positive patients who infected with HIV

Public title

Immune response to hepatitis B vaccine among HIV positive patients

Purpose

Diagnostic

Inclusion/Exclusion criteria

Isolated HBC Ab positive patients who infected with HIV
HBV DNA PCR positive, HBSAg positive, HBSAb positive
Patients were excluded

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan University of Medical Sciences

Street address

Fahmide Avenue

City

Hamadan

Postal code

Approval date

2015-04-21, 1394/02/01

Ethics committee reference number

lr.umsha.REC.1394.88

Health conditions studied

1

Description of health condition studied

chronic hepatitis B

ICD-10 code

B18.1

ICD-10 code description

Chronic viral hepatitis B without delta-agent Chronic (viral) hepatitis B

2

Description of health condition studied

Human Immunodeficiency Virus

ICD-10 code

B23.2

ICD-10 code description

HIV disease resulting in haematological and immunological abnormalities, not elsewhere classified

Primary outcomes

1

Description

Hbsab titer

Timepoint

pre and after vaccine, and repeated it in case of need

Method of measurement

quantitative serology

Secondary outcomes

1

Description

Probable Complication of Hepatitis B vaccine

Timepoint

will be done during the study

Method of measurement

Will be Measured by observing and questioning the patients

Intervention groups

1

Description

This study has no control group. Only for those who are just entering the study, merely intervention is 0.5 cc of Hepatitis B vaccine in turn of zero and if required Repeat it one and six months later

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

HIV Center of Hamadan

Full name of responsible person

Mohammad Mahdi Majzoobi

Street address

Clinic Shohada, Takhti Street

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Hamadan University of Medical Sciences

Full name of responsible person

Said Bashirian

Street address

Fahmide Avenue

City
Hamadan

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor of Hamadan 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
Hamadan University of Medical Sciences

Full name of responsible person
Mohammad Mahdi Majzoobi

Position
Assistant Professor

Other areas of specialty/work
Street address
Farshchian Hospital, Mirzade Eshghi Street

City
Hamadan

Postal code
Phone
+98 81 3827 4191

Fax
Email
mahdi.majzoobi@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamadan University of Medical Sciences

Full name of responsible person
Mohammad Mahdi Majzoobi

Position
Assistant Professor

Other areas of specialty/work
Street address
Fahmide Avenue

City
Hamadan

Postal code
Phone
+98 81 3827 4191

Fax
Email
mahdi.majzoobi@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Hamadan University of Medical Sciences

Full name of responsible person
mohammad mahdi majzoobi

Position
Assistant Professor

Other areas of specialty/work
Street address
Fahmide Avenue

City
Hamadan

Postal code
Phone
+98 81 3827 4191

Fax
Email
mahdi.majzoobi@umsha.ac.ir

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