Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 including1) 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

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Mohammad Mahdi Majzoobi
Name of organization / entity
Hamadan University of Medical Sciences, School of Medicine
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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 Siences
Street address
Fahmide Avenue
City
Hamadan
Postal code
Approval date
2015-04-21, 1394/02/01
Ethics committee reference number
Ir.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 Immunodeficeincy 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
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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