Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of Hepatitis B vaccination in developing Ab against Hepatitis B in patients with chronic kidney disease before dialysis

Protocol summary

Summary

This study compared the response rate of hepatitis B vaccination (HBV) in chronic renal failure (CRF) and end stage renal disease (ESRD) patients. One hundred and eighty participants were enrolled into this study. The CKD patients who were in pre-dialysis stage received a three, 40-µg dose course of the Recombivax HBV vaccine, intramuscularly, at 0, 1 and 6 months. The patients who were under hemodialysis received a four 40-µg dose course of the Recombivax HBV vaccine at 0, 1, 2 and 6 months, intramuscularly. Rate of seroconversion was evaluated 3 months after vaccination and compared between groups. Seroconversion was defined as hepatitis B surface antibody titer greater than 10 IU.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905163325N4**
Registration date: **2011-01-14, 1389/10/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-01-14, 1389/10/24

Registrant information

Name
Majgan Jalalzadeh
Name of organization / entity
Zanjan University Of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 24 1426 6934
Email address
jmojgan@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2008-03-20, 1387/01/01

Expected recruitment end date

2010-09-23, 1389/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Hepatitis B vaccination in developing Ab against Hepatitis B in patients with chronic kidney disease before dialysis

Public title

the effect of Hepatitis B vaccination in patients with chronic kidney disease

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age more than18 years old, presence of Chronic Kidney Disease in the stages of 2 to 4
Exclusion criteria: Presence of severe CKD which is predicted to result in end stage renal disease over a year, HBV positive, presence of lymphoprolifrative disease, receiving immunosuppressive drugs, previous HBV vaccination

Age

From **18 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **51**
Randomization (investigator's opinion)
N/A
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
Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences, Azadi Street, Zanjan, Iran
City
Zanjan
Postal code
Approval date
2010-04-14, 1389/01/25
Ethics committee reference number
19/3-236

Health conditions studied

1

Description of health condition studied
Chronic renal failure
ICD-10 code
N18
ICD-10 code description
Chronic renal failure

Primary outcomes

1

Description
Serum HBSAb
Timepoint
3 months after the last dose of vaccination
Method of measurement
Laboratory kits

Secondary outcomes

1

Description
HBS Ag
Timepoint
3 months after the last dose ofl anti HBV vaccination
Method of measurement
Laboratory kits

Intervention groups

1

Description
Intervention group: 40 micrograms HBV vaccine at the months of 0, 1, 2, 6 in patients with ESRD under dialysis
Category
Prevention

2

Description
Control group: 40 micrograms HBV vaccine at the months of 0, 1, and 6 in patients with chronic kidney disease at the stages of II - IV
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis center of Vali-e-Asr hospital
Full name of responsible person
Street address
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Ms. Eskandari
Street address
Faculty of Medicine, Zanjan University of Medical Sciences, Shahrak e karmandan street, Zanjan, Iran
City
Zanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Zanjan 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
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Person responsible for updating data

Contact

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