

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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- $\mu$ g dose course of the Recombivax HBV vaccine, intramuscularly, at 0, 1 and 6 months. The patients who were under hemodialysis received a four 40- $\mu$ g 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)

##### Phone

+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 than 18 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 lymphoproliferative 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 of 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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Fatemeh Mirzamohammadi

**Position**

Medical Student

**Other areas of specialty/work****Street address**

Faculty of medicine, Zanjan University of Medical Sciences, Zanjan, Iran

**City**

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**Postal code****Phone**

+98 912 610 9678

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fateme\_mm@yahoo.co.uk

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work****Street address**

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**City**

Zanjan

**Postal code****Phone**

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**Fax****Email**

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**Web page address****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*