

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the response to HBS Ag vaccine in chronic renal failure patients with different GFR levels

Protocol summary

Summary

The objective of this study was to investigate effects of vaccination against hepatitis B virus in inducing seroconversion in patients with chronic renal failure and different levels of kidney function. 150 patients including 50 patients with GFR between 40 and 60, 50 patients with GFR 15 and 40, and 50 patients with GFR less than 15 and also 150 healthy controls were included in the study. Three doses of recombinant HBS vaccines were injected intramuscularly at month 0, 3, and 6 with doses of 40 micrograms in intervention and 20 micrograms in control group. HBS Ab titers were measured and incidence of seroconversion was compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803121267N8**

Registration date: **2009-08-30, 1388/06/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-08-30, 1388/06/08

Registrant information

Name

Mojgan Borgheie

Name of organization / entity

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Urology and Nephrology Research Center

Expected recruitment start date

2007-08-23, 1386/06/01

Expected recruitment end date

2009-08-23, 1388/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the response to HBS Ag vaccine in chronic renal failure patients with different GFR levels

Public title

Comparison of the response to HBS Ag vaccine in chronic renal failure patients with different GFR levels

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Presence of Chronic Renal Failure, age between 18 and 85 years, negative HBS Ab, Exclusion criteria: Receiving immunosuppressive drug, previous HBV vaccinations

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran, I.R.

Street address

UNRC, No.101, 9th Boostan St., Pasdaran Ave.,
Tehran, I.R.Iran

City

Tehran

Postal code

1666677951

Approval date

empty

Ethics committee reference number

75

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

HBS Ab

Timepoint

4-8 weeks after the latest vaccine dose

Method of measurement

lab test

Secondary outcomes

empty

Intervention groups

1

Description

Vaccination with Engrix with dosage of 40 milligramgr, IM
in months 0, 1, 6

Category

Prevention

2

Description

Vaccination with Engrix with dosage of 20 milligram, IM
in months 0, 1, 6

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Labafi Nejad Hospital

Full name of responsible person

Street address

Labafi Nejad Hospital, 9th Boostan St., Pasdaran Ave.,
Tehran, I.R.Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran, I.R.

Full name of responsible person

Shabnam Golshan

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Urology and Nephrology Research Center (UNRC), Shahid
Beheshti University, M.C.(SBMU), Tehran, I.R.

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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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