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 hepatits 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 Mediacal Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 2256 7222

Email address
research@unrc.ir

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 yea, 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
City
Tehran

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

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

Full name of responsible person

Dr Mitra Mahdavi Mazde

Position

Assistant professor

Other areas of specialty/work

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Dr Mozhgan Borgheie

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General physician

Other areas of specialty/work

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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