

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effects of Pegylated Filgrastim (PEG-G-CSF) Adjuvant on Improving Response to Hepatitis B Vaccine and HBs-Ab Serum Levels in Non-responder Chronic Hemodialysis Patients- A Randomized Double-Blind Clinical Trial

Protocol summary

Study aim

1) Determining the HBs-Ab serum levels and improving the response rate to the hepatitis B vaccine in hemodialysis patients receiving PEG-G-CSF adjuvant 2) Determining the improved response rate to the hepatitis B vaccine in hemodialysis patients receiving PEG-G-CSF adjuvant by age, sex, and underlying diseases

Design

A controlled, double-blind, randomized, phase 2 clinical trial will be conducted on 80 hemodialysis patients. The block randomization method and SAS 9.3 software will be used for randomization.

Settings and conduct

All hemodialysis centers affiliated with SUMS will participate in this trial. Participants, outcome assessors, and statisticians will be blinded to treatment allocation. Randomization will be computer-generated by an independent data administrator.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range between 18-70 years
Dialysis adequacy 3 times a week
Negative serology for HBsAg, total anti-HBC, anti HCV, HIV
Receiving 3 IM doses of HBV vaccination and HBS-Ab titer <10 IU/L (non-responder patients)
Exclusion criteria: Positive serology for HBsAg, total anti-HBC, anti HCV, HIV
Prior use of any immunomodulatory agents like steroids/vaccine adjuvants and blood transfusion in last 6 months
Scheduled to have kidney transplantation within 3 months

Intervention groups

Non-responder Hemodialysis patients will be randomized in a 1:1 ratio into 2 groups: Control Group received three booster dose of HBV vaccine IM (0, 2nd, 6th months), Adjuvant Group received a dose 6 mg/0.6 mL subcutaneous PEG-G-CSF (PegaGen®, CinnaGen) 24 hours before first booster dose of HBV vaccine IM, and

received other two booster dose in the 2nd and 6th months. HBS-Ab was measured 1 month after the last two boosters (3rd, 7th months).

Main outcome variables

Antibody to hepatitis B surface antigen
Response rates to vaccine
Total leukocyte and neutrophil count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090701002113N4**

Registration date: **2025-12-19, 1404/09/28**

Registration timing: **prospective**

Last update: **2025-12-19, 1404/09/28**

Update count: **0**

Registration date

2025-12-19, 1404/09/28

Registrant information

Name

Jamshid Roozbeh

Name of organization / entity

Shiraz university of medical sciences

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roozbehj@sums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-12-31, 1404/10/10

Expected recruitment end date

2026-08-01, 1405/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Pegylated Filgrastim (PEG-G-CSF) Adjuvant on Improving Response to Hepatitis B Vaccine and HBs-Ag Serum Levels in Non-responder Chronic Hemodialysis Patients- A Randomized Double-Blind Clinical Trial

Public title

PEG-G-CSF in Non-responder Hemodialysis Patients HBs-Vaccination

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range between 18 and 70 years Patients with dialysis adequacy 3 times a week Patients with negative serology for HBsAg, total anti-HBC, anti HCV, HIV 1 and 2 Receiving 3 IM doses of HBV vaccination and HBS-Ab titer <10 IU/L (non-responder patients) Patients of chronic renal failure with serum creatinine >2.0 mg/dL, Glomerular filtration rate (GFR) <60 mL/min on hemodialysis (HD)

Exclusion criteria:

Patients with positive serology for HBsAg, total anti-HBC, anti HCV, HIV 1 and 2 Prior use of any immunomodulatory agents like steroids/vaccine adjuvants in last 6 months Receiving blood transfusion in previous 6 months Scheduled to have kidney transplantation within 3 months History of active cancer or active infection under treatment Pregnancy, childbearing potential during the study period, or breastfeeding

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed by an independent statistician using a computerized random number generator via the SAS 9.3 software block randomization

method (SAS Institute, Cary, NC, USA). Eligible participants will be randomly assigned 1:1 to a control group or a treatment group. All individuals who meet the inclusion/exclusion criteria at the first visit will be assigned to a group using the blocked randomization method, based on the allocation codes. Each patient will be assigned a unique study number. An independent data administrator who is not involved in clinical practice or patient recruitment will generate the randomization sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, a double-blind design will be implemented. Participants, researchers, outcome assessors, and statisticians will remain unaware of the treatment allocation to prevent any bias resulting from expectations or preconceived notions. To ensure this, randomization lists will be generated by an independent data manager who is not involved in the study, using a computerized system. After generation, these lists will remain concealed from the researchers and other study team members and will be kept strictly confidential. Treatment allocation to participants will be done automatically by the software in a centralized manner, without human intervention. As a result, none of the researchers or outcome assessors will have knowledge of the treatment assigned to the participants throughout the study, and this process will remain confidential until the final analysis and result reporting.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Medicine - Shiraz University of Medical Sciences

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7th floor, University Central Building, Zand street

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7134814336

Approval date

2024-06-16, 1403/03/27

Ethics committee reference number

IR.SUMS.MED.REC.1403.176

Health conditions studied

1

Description of health condition studied

End-stage Kidney disease

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description

HBs-Ab serum levels

Timepoint

Before first vaccin booster and one month after the last two vaccine boosters (3rd, 7th months)

Method of measurement

HBs-Ab serum levels will be measured by ELISA methods. 5 ml of blood will be collected in K2-EDTA tubes and HBs-Ab will be measured before PEG-G-CSF and the first vaccine booster injection, and 1 month after the last two boosters.

2

Description

Response rate to hepatitis B vaccine

Timepoint

One month after the third booster dose (month 7 of the study period)

Method of measurement

Calculating the percentage change from baseline antibody levels

Secondary outcomes

1

Description

Total leukocyte count

Timepoint

One month after the third booster dose (month 7 of the study period)

Method of measurement

Performing CBC Diff test for patients

2

Description

Neutrophil count

Timepoint

One month after the third booster dose (month 7 of the study period)

Method of measurement

Performing CBC Diff test for patients

Intervention groups

1

Description

Intervention group: will receive a dose of 6 mg/0.6 mL subcutaneous PEG-G-CSF 24 hours before the first booster dose of HBV vaccine IM, and receive the other two booster doses in the 2nd and 6th months.

Category

Treatment - Drugs

2

Description

Control group: will receive three booster dose of HBV vaccine IM (0, 2nd, 6th months)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Teaching Hospital

Full name of responsible person

Jamshid Roozbeh

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz University of Medical Sciences

Proportion provided by this source

30

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

2

Sponsor

Name of organization / entity

CinnaGen

Full name of responsible person

Mehdi Ahmadi

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No. 34, Sepehr Street, Farahzadi Boulevard, West
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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

CinnaGen

Proportion provided by this source

70

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Masjedi

Position

Professor of Nephrology

Latest degree

Specialist

Other areas of specialty/work

Nephrology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Fatemeh Masjedi

Position

Assistant Professor

Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

Only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Reporting data based on our analyses in the form of books, reviews, and meta-analyses.

From where data/document is obtainable

Contact us with the following email:
masjedi_f@sums.ac.ir

What processes are involved for a request to access data/document

Maximum two weeks after email sending and sufficient explanation of how the data will be used.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Jahrom University of Medical Sciences

Full name of responsible person

Sara Rahmanian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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